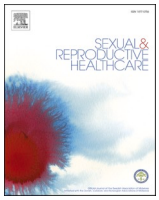
Sexual & Reproductive Healthcare 42 (2024) 101033

Contents lists available at ScienceDirect

Sexual & Reproductive Healthcare

journal homepage: www.elsevier.com/locate/srhc



Investigating the associations between early labour onset symptoms and self-diagnosed labour onset in a cohort study of primiparas

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ARTICLE INFO

Keywords:
Early labour
Transition phase
Onset of labour
Midwifery

ABSTRACT

Objective: The early recognition of possible labour onset symptoms may be pivotal to identifying the beginning of early labour and are usually recognised by the birthing women themselves. The present study illustrates the interrelationship among five labour-onset symptoms and explores the association of these labour-onset symptoms with the self-diagnosed labour onset of primiparas.

Methods: A prospective cohort study on a sample of 69 primigravida in Giessen, Germany, expecting spontaneous onset of labour at term. The participants filled in a diary from ≥37 + 0 weeks gestation until self-diagnosed labour onset. Descriptive, bivariate and inferential analysis explored association of labour onset symptoms with self-diagnosed labour onset while accounting for maternal and newborn characteristics.

Results: Self-diagnosed labour onset was positively associated with all symptoms and clinical characteristics, apart from irregular pain and maternal weight and age. Moreover, regular pain was negatively correlated with irregular pain; having regular pain increased the odds of self-diagnosed labour onset substantially (OR: 10.18, 95 % CI: 2.39–66.27), followed by gastrointestinal symptoms (OR: 2.07, 95 % CI: 0.40–13.10) and emotional symptoms (OR: 2.05, 95% CI: 0.30–13.98).

Conclusion: Being the initiator of intrapartum care without any birth experience, primiparas are prone to experiencing dissatisfaction in care and may enter professional care too late or too early. The present study showed that regular pain may signify primiparas to self-diagnose labour onset within 24 h and indicate early labour symptoms that may be relevant for a self-diagnosed labour onset.

Introduction

The definition of the onset of early labour remains challenging [1–3]. Midwives use cervical dilatation, regular and continuous uterine contractions and fluid loss as parameters to determine early labour onset [4,5]. These parameters might be associated with a possible need for midwifery care [6–9]. Women may experience symptoms that can mark the transition into early labour. The transition into early labour has been described to be characterised by several labour onset symptoms within four days before birth (8). During this transition, primiparas need to decide when it is time to seek professional care, which usually happens when labour starts subjectively. When labour onset symptoms are experienced by women, they are deemed to be self-diagnosed symptoms in contrast to professionally confirmed objective symptoms. Self-diagnosed symptoms are usually experienced before attending professional care. So far one study addressed the time gap between women's self-diagnosed symptoms as the beginning of labour onset and the assessment of midwives [6].

Gross and colleagues found that the women's assessment of labour onset disagreed with that of the midwives, with nulliparas and multiparas reporting a (median) four-hour and two-hour earlier labour onset, respectively, than the midwives [6]. Most women identified the start of labour through contractions, membrane leakage, and irregular pain and reported different labour onsets in hours regarding these indications [6]. Only a minority of women, 10 % of both nulliparae and multiparae, agreed with their midwives that rupture of membranes was the lead symptom for the onset of labour [6].

Further studies on women's symptoms mentioned regular or recurrent pain, vaginal discharge (mucusy or bloody show, watery loss), emotional symptoms (e.g. sleep disturbance) and gastrointestinal

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https://doi.org/10.1016/j.srhc.2024.101033
Received 3 May 2024; Received in revised form 5 September 2024; Accepted 7 September 2024
Available online 10 September 2024

symptoms as potential signals for labour onset; however, without researching their association with labour onset associations to further parameters [1,3,8,10]. There is numerous literature on women's views regarding their symptoms and experiences of early labour, but the time gap between labour onset symptoms and the subjective start of labour onset is still missing.

Recent epidemiological studies have mostly investigated the duration of early labour or first-stage labour but not on the timing of women's subjective early labour onset [2,11,12]. These studies focused on uterine contractions and cervical ripening to define labour onset, and measured clinical interventions and outcomes to differentiate between too long or too short early labour duration before hospital admission. Tilden et al. [2] and Janssen and Weissinger [11], referred to self-reported painful contractions to distinguish between early and late labour onset. Kjerulff et al. [12] solely focused on cervical dilatation to differentiate between early (as in the latent phase) and late (as in the active phase) admission to the hospital; however, without accounting for the timing of women's subjective onset of labour.

However, a retrospective cohort study by Ängeby et al. [13] used women's self-reported labour onset in hospital records to describe the prevalence of a prolonged latent phase (>18 h) in primiparas. They found that for nulliparous women, the mean duration of the latent phase was 13.9 h with a range between 0 and 96 h (standard deviation: 15.1) until the active first stage of labour was reached (defined as either 3 to 4 contractions per 10-minute period, or rupture of membranes, or dilatation of the cervix of 3–4 cm). However, specific symptoms experienced by primipras at the subjective labour onset were not recorded [13].

The early recognition of possible labour onset symptoms may work as a special key to identifying the beginning of early labour and are usually detected by the birthing women within their private environment. Grylka-Baeschlin and Mueller [9] reported that pregnant women faced a huge variety of physical and emotional symptoms at the beginning of labour, from very mild to very painful contractions or from positive emotions to fear. The authors underlined the individual experience of early labour in birthing women [9,3].

However, primiparous women often feel uncertain regarding their self-diagnosed labour onset and the right time to seek midwifery care [8]. Women want to be informed and reassured when experiencing feelings of uncertainty in early labour [14]. A secondary data analysis by Stone and Downe [15] showed that providing support to women during this phase is crucial. This support may come in various forms, such as emotional, physical, or informational. Ensuring that women receive appropriate assistance during this phase may positively impact their overall experience of labour and birth [15]. Edwards, Way and Hundley [16] support this view and argue that women are substantially more likely to progress spontaneously in subsequent labour when supported positively at the beginning of labour [16].

A previous study by Gehling et al. [8] revealed that some primiparas experienced a self-diagnosed early labour onset from 32 days before birth. While the certainty of early labour onset increased closer to birth, labour onset symptoms were experienced throughout this time. However, the relevance of labour onset symptoms in combination with a self-diagnosed labour onset was described within four days before birth, and associated symptoms were regular and irregular pain, symptoms of vaginal loss and emotional symptoms [8]. It was discussed that early labour symptoms may motivate women to contact health professionals in order to confirm the experienced beginning of labour. Hence, a diagnosis of labour onset based on clinical parameters such as cervical ripening and/or fetal descent is only possible after maternal contact and motivation.

With the intention to address the knowledge gap concerning early labour onset symptoms and labour onset as experienced by birthing women, the present study explored associations between labour onset symptoms and the self-diagnosed definition of early labour onset in primiparas.

Methods

A prospective cohort study was conducted between July 2020 and March 2021 on a convenient sample of primiparous women in the region of Giessen, Germany [8]. The study was ethically approved by Hannover Medical School, Germany (# 7369, February 2020). Each participant provided informed consent before entering the study. Data collection was anonymous, and data protection was confirmed by the data protection office of Hannover Medical School in Germany.

Eligibility criteria included primiparous women expecting spontaneous onset of labour from 37 completed gestational weeks. Eligible participants received a printed questionnaire with a stamped return envelope during antenatal classes and personal contacts. The recruitment of primiparas was anticipated in July 2020 through personal contact in antenatal classes by the main author. Due to the beginning of the SARS-COV-2 pandemic antenatal classes were often changed into online classes. Therefore, primiparas were also recruited through personal contact online (n = 22 out of 41 distributed questionnaires; 53.6 %). Unfortunately, many antenatal classes were closed to prevent infection in this vulnerable group, so it was not possible to reach primiparas personally. We, therefore, asked cooperating midwives via snowball sampling to distribute further questionnaires, such as during antenatal check-ups (n = 47 out of 161 distributed questionnaires; 29.2 %). We also had to reduce the anticipated sample to not less than 150 participants due to financial and time restrictions. Data collection was closed when 202 questionnaires were distributed in January 2021.

The questionnaires had a structured form that included three main sections:

- The first section represented maternal and birth-related factors (i.e., maternal age, education, nationality, weight and height (BMI), planned place and mode of birth and the due date).
- The second section comprised a daily questionnaire of nine labour onset symptoms (i.e., regular or irregular pain; vaginal discharge of either watery, mucusy or bloody liquid; gastrointestinal symptoms or nausea; emotional unrest or sleep disturbance) as introduced by Gross et al. [10], with instructions to mark the date and time of onset and end of each symptom. Also a free text option was given for additional symptoms. Furthermore, participants were asked daily about self-diagnosis and certainty of labour onset. This information was asked to be given in the diary-based questionnaire every day from $\geq 37 + 0$ weeks gestation until labour onset was experienced or the baby was born.
- The third section included items of the official self-carried records (Mutterpass) reporting date, time, place and mode of birth as well as data for the newborn. Participants were instructed to complete the third section at a convenient time after birth and then return the questionnaire in the stamped return envelope to the first author.

Development and testing of the questionnaire

The diary-based questionnaire was developed in the Midwfery Research and Education Unit of Hannover Medical School after extensive consultation with the last author and other midwifery researchers. The developed questionnaire was tested in a pilot study on 66 primiparas with a singleton-term pregnancy. A feedback form about the usability and completeness of the questionnaire was sent out to four volunteering participants, of whom three gave feedback. Then, the questionnaire was further improved by requiring the participant to include the date and time when a symptom began and possibly ended, as well as an option to fill in other experienced symptoms that were not listed. Through expert discussions, the symptoms of continuous pain and vomiting were excluded, and gastrointestinal symptoms next to nausea, as well as emotional symptoms next to sleep disturbance, were summarised. The questionnaire was tested for usability but was non-

validated before conducting this exploratory study.

Sample size calculation

In the region of Giessen, approximately 5000 babies are born within a year. Since the first author lives and works in the region, birth rates of the different hospitals and Midwifery Led Units were estimated and combined. The outcome of interest was primiparous women with a singleton, term and healthy baby, so we reduced the study population to approximately 4000. In order to represent a population of 4,000 with a confidence level of 95 % and a margin of error of 5 %, a sample size of 350 was calculated using the online calculator Survey King [17]. After sample size calculation, the SARS-COV-19 pandemic also hit the region of Giessen with restrictions of personal contact. Due to these circumstances, the aimed sample size was reduced to at least 175 (half of the previously calculated).

Data preparation

Symptoms were grouped into five categories (regular pain, irregular pain, symptoms of vaginal loss, emotional symptoms, and gastrointestinal symptoms) according to their main characteristics. The self-diagnosed labour onset was the outcome of the present study and was dichotomised from a five-point Likert scale to a binary variable, with present self-diagnosed labour onset including the levels 'yes, a little'; 'yes, quite a lot'; and 'yes certainly', and absent self-diagnosed labour onset referring to the levels 'no' and 'not sure'.

Analysis

Descriptive analysis: characteristics, labour onset symptoms and certainty

All maternal and newborn characteristics were summarised in the sample and by self-diagnosed labour onset (i.e., present or absent) using measures of central tendency (mean and median) and dispersion tendency (standard deviation, interquartile range, and range) for the continuous characteristics, and absolute and relative frequencies for the categorical ones. We explored the extent and pattern of missing data using a tile plot on the missing characteristics for each participant, a crossed bar plot on the frequency of unique missing data patterns, and a bar plot on the percentage of missing data by self-diagnosed labour onset for characteristics with missing data. Missing data were also summarised using absolute and relative frequencies in the corresponding characteristics. We created violin plots with integrated box plots and dots to illustrate the distribution of the continuous characteristics in the sample and by self-diagnosed labour onset. For the categorical characteristics, stacked bar plots were created to present the distribution of the self-diagnosed labour onset in each level of the characteristics.

We created a Kaplan-Meier plot to illustrate the Likert scale on certainty of subjective labour onset during the relevant days before birth. The certainty of self-diagnosed labour onset was distinguished into 'no', 'yes, a little', 'yes, quite a lot', 'yes, certainly', and 'not sure'.

Bivariate exploratory analysis

We created a correlation matrix to illustrate the interrelationship among the five groups of labour onset symptoms and reported the phi coefficient (φ) to measure the magnitude of the association. Since a phi coefficient has the same range of values as Pearson's, we used the tentative suggestions of Schober et al. [18] to interpret the magnitude of the correlations: an absolute value in the interval (0.00, 0.10), (0.10, 0.38), (0.38, 0.68), (0.68, 0.89), and (0.89, 1.00) may reflect negligible, weak, moderate, strong and very strong correlation, respectively. The sign of the phi coefficient indicated whether the association was positive or negative.

Inferential analysis

A multivariable binary logistic regression model was conducted to explore the association between the self-diagnosed labour onset (dependent, binary variable) and the following independent variables:

- two continuous maternal characteristics: age in years, and weight in kg.
- two newborn characteristics: the gestational age in weeks (continuous) and the newborn's associated sex (female vs. male).
- five groups of binary labour onset symptoms (present vs. absent): regular pain, irregular pain, emotional symptoms, symptoms of vaginal loss and gastrointestinal symptoms;

The height of women was initially considered in the model, but due to multicollinearity, manifested as a very large standard error, this variable was dropped from the model. The continuous variables were centred around their mean to facilitate interpretation.

To address possible separation, we considered Firth's bias correction method, referred to as Firth's correction, which implements a profile penalised likelihood to obtain the *corrected* 95 % confidence intervals [19–21]. Separation implies that the categorical independent variable can predict (almost perfectly) the dependent (binary) variable. We also illustrated the results obtained by conducting a binary logistic regression based on maximum likelihood methods, referred to as '*classical' logistic regression*, to gauge the implications of possible separation in the affected variables and offer transparency on the methods planned and performed. We interpret the results obtained from Firth's correction.

The associations between each characteristic and the self-diagnosed labour onset were measured using the odds ratio (OR) and were accompanied by a 95 % confidence interval (CI). We inferred the association to be statistically significant if the 95 % CI did not include the value of no association (i.e., an odds ratio of one), which coincides with a p-value less than the selected significance level (here: 5 %); otherwise, the association was inferred to be statistically non-significant. Since the present study was exploratory, inferences on statistical significance aim to explore rather than confirm the corresponding associations. The latter is appropriate in a randomised controlled trial.

We created a forest plot to illustrate the results (OR and 95 % CI) from Firth's correction and 'classical' logistic regression, but we emphasised the interpretation of Firth's correction.

We did not address the missing data, for instance, using multiple imputation, since the missingness rate was very low, which probably would not materially affect the estimated results. Therefore, listwise deletion was performed to run the models, which corresponds to assuming that missing data are missing completely at random.

All analyses were performed using the statistical software R, version 4.3.0 [22]. The R packages *gtsummary* [23] and *ggplot2* [24] were used to create Table 1 and all Figures. The correlation matrix was created using the R package *ggcorrplot* [25]. Missing data exploration and visualisation was employed using the R package *naniar* [26]. Firth's bias correction was implemented using the R package *logistf* [27].

Results

The response rate was 34,2 %, calculated as a percentage of 69 returned questionnaires out of 202 distributed questionnaires.

Descriptive results: characteristics, labour onset symptoms and certainty

Table 1 summarises the characteristics of the 69 primiparas in the whole sample and by the status of self-diagnosed labour onset. Specifically, the primiparas' age ranged from 20 to 40 years (median: 31) and was overall similarly distributed between those with and those without a self-diagnosed labour onset. Their weight ranged from 49 to 105 kg (median: 73) and was slightly higher among those without self-

Table 1
Demographic and clinical characteristics of the mother and newborn.

Characteristic	Overall (N = 69)	Self-diagnosed labour onset on the last day of completion of the questionnaire	
		Yes (N = 49)	No (N = 20)
Age (in years)			
Mean (StD)	31.0 (3.7)	30.0 (4.0)	31.0 (2.8)
Median (IQR)	31.0 (29.0, 33.0)	30.0 (28.0, 33.0)	31.0 (29.0, 32.3)
Range	(20.0, 40.0)	(20.0, 40.0)	(26.0, 38.0)
Weight (in kg)			
Mean (StD)	73 (14)	72 (14)	77 (15)
Median (IQR)	73 (66, 83)	72 (63, 80)	77 (68, 83)
Range	(49, 105)	(49, 105)	(50, 104)
Missing (%)[1]	4 (5.8)	2 (4.1)	2 (10.0)
Height (in m)			
Mean (StD)	1.69 (0.06)	1.69 (0.06)	1.70 (0.07)
Median (IQR)	1.69 (1.65, 1.72)	1.69 (1.65, 1.72)	1.70 (1.65, 1.73)
Range	(1.56, 1.82)	(1.59, 1.82)	(1.56, 1.80)
Missing (%)[1]	1 (1.4)	0 (0.0)	1 (5.0)
BMI (in kg/m^2)			
Mean (StD)	25.0 (4.7)	25.0 (4.7)	26.0 (4.8)
Median (IQR)	25.0 (23.0, 28.0)	25.0 (22.0, 28.0)	26.0 (24.3, 29.8)
Range	(18.0, 37.0)	(18.0, 37.0)	(19.0, 37.0)
Missing (%)[1]	4 (5.8)	2 (4.1)	2 (10.0)
Gestational age at birth (in weeks)			
Mean (StD)	40.00 (1.11)	40.10 (1.07)	39.20 (1.18)
Median (IQR)	40.00 (39.20, 40.50)	40.10 (39.30, 40.50)	39.20 (38.53, 40.43)
Range	(37.00, 41.30)	(37.00, 41.30)	(37.00, 41.30)
Newborn sex[1]			
Female (%)	30 (46)	23 (50)	7 (37)
Male (%)	35 (54)	23 (50)	12 (63)
Missing (%)	4 (5.8)	3 (6.1)	1 (5.0)
Regular pain			
Yes (%)	44 (64)	42 (86)	2 (10)
No (%)	25 (36)	7 (14)	18 (90)
Irregular pain			
Yes (%)	31 (45)	16 (33)	15 (75)
No (%)	38 (55)	33 (67)	5 (25)
Symptoms of vaginal loss			
Yes (%)	52 (75)	40 (82)	12 (60)
No (%)	17 (25)	9 (18)	8 (40)
Emotional symptoms			
Yes (%)	44 (64)	33 (67)	11 (55)
No (%)	25 (36)	16 (33)	9 (45)
Gastrointestinal symptoms			
Yes (%)	25 (36)	22 (45)	3 (15)
No (%)	44 (64)	27 (55)	17 (85)

IQR, interquartile range; StD, standard deviation.
[1] Result are presented in absolute frequencies and relative frequencies (in parenthesis).

diagnosed labour onset in terms of median and interquartile range. The height was similarly distributed among the primiparas with self-diagnosed labour onset and those without, ranging from 1.56 to 1.82 m (median: 1.69) in this sample. Based on the BMI index, the primiparas ranged from underweight to obese (range: 18.0–37.0), with those not experiencing self-diagnosed labour onset having slightly higher BMI index values. Supplementary Figure S1 illustrates the violin plots of the characteristics above in the whole sample and for each self-diagnosed labour onset status.

Gestational age at birth ranged from 37.0 to 41.30 (median: 40) and was similarly distributed regarding the self-diagnosed labour onset status (Table 1). More than half the women gave birth to male newborns (54 %, n = 35): half of those with self-diagnosed labour onset status (n = 23) and 63 % (n = 12) of those without self-diagnosed labour onset status gave birth to male newborns. Supplementary Figure S2 presents the violin plot of gestational age at birth and the stacked bar plot of newborn sex in relation to the self-diagnosed labour onset status.

Regarding the distribution of labour onset symptoms, 64 % of the participants experienced regular pain. Expectantly, most women with self-diagnosed labour onset experienced regular pain (86 %), and most women without self-diagnosed labour onset did not report having experienced regular pain (90 %). The opposite was observed for irregular pain: 45 % of the women experienced irregular pain, with 75 % of those without a self-diagnosed labour onset reporting irregular pain as compared to 33 % of women with a self-diagnosed labour onset. Most women had symptoms of vaginal loss (75 %), and emotional symptoms (64 %), and this pattern persisted regardless of whether the women had a self-diagnosed labour onset or not (82 % versus 60 %). Lastly, most women did not experience any gastrointestinal symptoms (64 %); this tendency pertained to women with self-diagnosed labour onset (55 %) and those without (85 %). Supplementary Figure S3 illustrates the distribution of the different symptoms regarding the status of self-diagnosed labour onset.

Fig. 1 presents the different levels of certainty about their labour onset on the percentage of 69 primiparas as recorded by the end of their questionnaire with a Kaplan-Meier plot. Overall, the higher the certainty of the woman about her labour onset, the shorter the duration of filling in the questionnaire. Specifically, those women who reported not having a self-diagnosed onset required the most time before they stopped filling in their questionnaire (red line), followed by those who were unsure about their labour onset (purple line) and those reporting being a little certain about the onset of their labour (dull yellow line). Primiparas who stopped filling in the questionnaire within the last 10 days, those who were quite a lot certain about the onset of their labour (green line), required slightly more days than those who were very certain (blue line).

Missing data exploration

Missing data were very low, corresponding to 1.2 % in the dataset and pertaining only to the following independent variables: weight, newborn sex and height (Supplementary Figure S4). One woman did not report her height and weight, three women did not report their weight, and for four women, the newborn sex was not recorded (Supplementary Figure S5). The percentage of missing data in these characteristics by self-diagnosed labour onset showed that 4 % of the women with self-diagnosed labour onset did not report their weight, and 6 % did not report their newborn sex (Supplementary Figure S6). Of those without a self-diagnosed labour onset, 10 % did not report their weight, and 5 % did not report their height or newborn sex (Supplementary Figure S6).

Bivariate analysis

The correlation coefficient matrix displayed some interrelation among the five labour onset symptoms, ranging from weak to moderate (Fig. 2). Specifically, regular pain was negatively correlated (and statistically significant) with irregular pain, manifesting a moderate correlation ($\varphi = -0.53$). Logically a woman can not experience both pain symptoms at the same time and once irregular pain becomes regular this symptom switches to regular pain, hence it is correlated negatively. A moderate and statistically significant correlation, but of a slightly smaller magnitude, was found for symptoms of vaginal discharge and emotional symptoms, exhibiting a positive correlation ($\varphi = 0.48$). On the contrary, a negligible correlation was found between gastrointestinal symptoms and irregular pain ($\varphi = -0.01$), symptoms of vaginal discharge and irregular pain ($\varphi = 0.04$), and emotional symptoms and regular pain ($\varphi = 0.06$).

Inferential analysis

Fig. 3 presents the forest plot with the results from the two exploratory regression analyses. The two analyses differed substantially in the regression coefficient (OR and coverage of the 95 % CIs) for regular pain, with Firth's correction yielding a smaller and more precise OR at 10.18 as compared to the 'classical' logistic regression (OR of 24.88). The different results may be attributed to some evidence of separation: women with regular pain were more likely to have reported self-

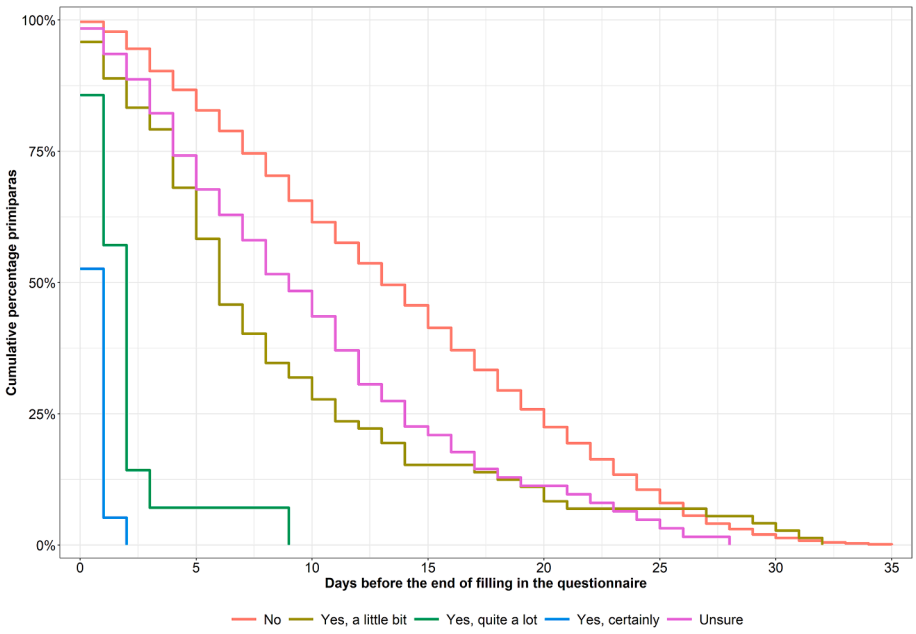

Fig. 1. Kaplan-Meier plot on the cumulative percentage of primiparas expressing their degree of certainty about their labour onset recorded by the end of their questionnaire. The y-axis refers to the cumulative percentage of primiparas, and the x-axis to the number of days before the participants stopped filling in the questionnaire. Different colours of the lines in the legend indicate a different level of certainty (No; Yes, a little bit; Yes, quite a lot; Yes, certainly; Unsure).

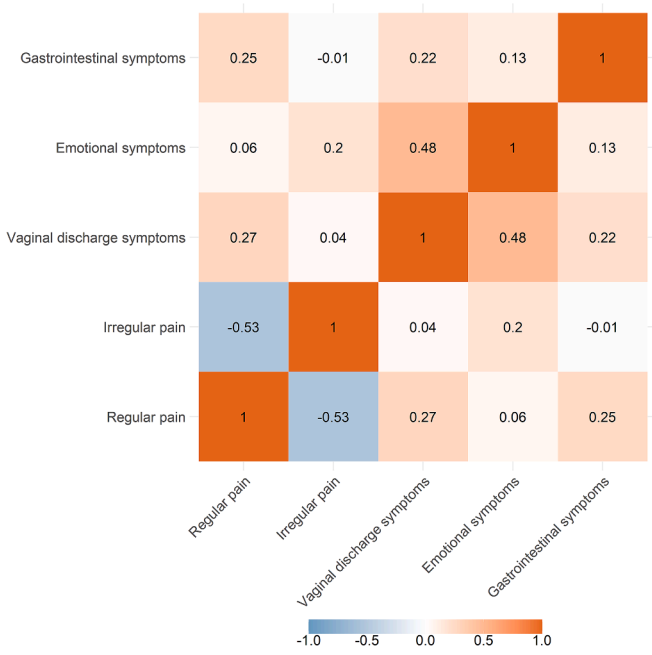

Fig. 2. A correlation matrix with the phi coefficient (φ) among five labour onset symptoms (gastrointestinal symptoms, emotional symptoms, vaginal discharge symptoms, irregular pain, and regular pain). The cells' colour indicates the correlation's magnitude and direction, with blue and red colours pointing to a negative and positive correlation, respectively. The darker the colour, the stronger the correlation. The key legend below the correlation matrix matches the colours with the direction and magnitude of the correlation.

diagnosed labour onset (95 %, 42 out of 44 in Table 1), whereas women without regular pain were more likely not to have reported self-diagnosed labour onset (72 %, 18 out of 25 in Table 1).

Regular pain was positively associated with the odds of self-diagnosed labour onset and comprised the only statistically significant regression coefficient in the model but with a large confidence interval: the odds of self-diagnosed labour onset were 10.18 times higher in women reporting regular pain than those without regular pain (95 % CI: 2.39–66.27). Furthermore, the odds of self-diagnosed labour onset were 2.07 (95 % CI: 0.40–13.10) and 2.05 (95 % CI: 0.30–13.98) higher in women reporting gastrointestinal and emotional symptoms than those without any such symptoms, respectively; however, both associations were statistically non-significant and had large confidence intervals reflecting substantial uncertainty in the estimation. Gestational age, newborn sex and symptom discharge were also positively associated with the odds of self-diagnosed labour onset but to a lower magnitude than the previous symptoms, and the associations were statistically non-significant. Specifically, women with a later gestational age had 37 % higher odds of self-diagnosed labour onset than those earlier in labour (OR: 1.37, 95 % CI: 0.67–3.15). Women with female newborns had 25 % higher odds of self-diagnosed labour onset than those with male newborns (OR: 1.25, 95 % CI: 0.30–5.50). Finally, women experiencing symptoms of vaginal discharge had 27 % higher odds of self-diagnosed labour onset than those without symptoms of vaginal discharge (OR: 1.27, 95 % CI: 0.18–8.14).

The remaining characteristics revealed a negative or very low association with the odds of self-diagnosed labour onset, with the evidence being statistically non-significant. Women with more weight had 1 % lower odds of self-diagnosed labour onset than those with less weight (OR: 0.99, 95 % CI: 0.94–1.05). Similarly, older women had 4 % lower odds of self-diagnosed labour onset than younger women (OR: 0.96, 95 % CI: 0.74–1.21). Lastly, having irregular pain led to 53 % lower odds of self-diagnosed labour onset than not having any irregular pain at all (OR: 0.47, 95 % CI: 0.06–3.59).

Discussion

This study prospectively examined labour onset symptoms using a series of analyses, including their intercorrelation and associations with the experience of self-diagnosed labour onset in primiparas. The regression analyses showed that regular pain may be associated with self-diagnosis of labour onset within 24 hrs. Hence, primiparas may have a good decision-making mechanism and can self-predict entering labour quite accurately within 24 hrs once they have regular pain. This aligns

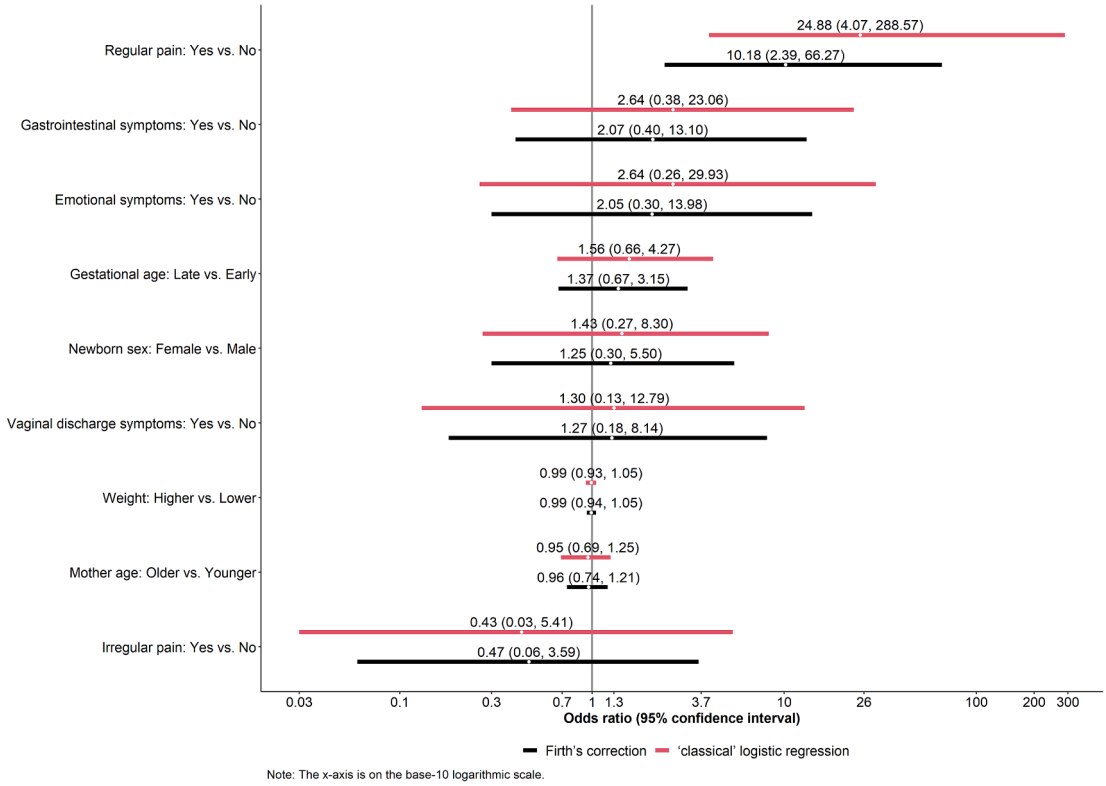

Fig. 3. A forest plot on the odds ratio of self-diagnosed labour onset (white circles) and 95 % confidence intervals (horizontal lines) under multivariable binary logistic regression with Firth's correction (black lines) and the 'classical' multivariable binary logistic regression (red lines). 95 % confidence intervals crossing the vertical grey reference line correspond to statistically non-significant results. Results are sorted in descending order of the odds ratios. The x-axis is on the base-10 logarithmic scale. For each variable in the y-axis, the odds ratio refers to the first versus the second category; for instance, the odds of self-diagnosed labour onset in women with regular pain (Yes, the first category) versus those without regular pain (No, the second category).

with the advice given in antenatal classes [28,29]. Primiparas are well able to identify labour onset independent of cervical dilation or other clinical and interventive parameters based on their self-diagnosed feeling alone [3,6,8,13].

All other symptoms were found to be statistically non-significantly associated with a self-diagnosed labour onset in the logistic regression models, probably due to the small sample considered for the analysis. Interestingly, gastrointestinal symptoms and emotional symptoms appeared to be positively associated with a self-diagnosed labour onset, corresponding to a substantial OR of approximately 2. However, irregular pain was found to be negatively associated with self-diagnosed labour onset, which could indicate that primiparas knew or learned (in antenatal classes) that irregular pain does not necessarily cause the baby to be born.

Our analysis also revealed a moderate negative correlation between regular and irregular pain, implying that the more irregular pain was felt, the less regular pain was indicated and vice versa. Obviously, it is unlikely that both regular and irregular pain were felt simultaneously but this finding may point to the interdynamics of early labour, suggesting midwives to wait until regular contractions to define active labour onset [4,5,13]. Primiparas may be more aware of pain patterns once irregular pain is experienced and wait for the appearance of regular pain before feeling or indicating that labour has started. That could explain why only the symptom of regular pain was associated with the indication of a self-diagnosed labour onset based on a large OR value. In accordance with the information given by midwives, such as in antenatal classes, the experience of less irregular pain may have led to the experience of more regular pain, which then may have initiated a self-diagnosed labour onset in our convenience sample of primiparas [3,8,28,29].

Looking at the association between labour onset symptoms, symptoms of vaginal loss were moderately associated with emotional symptoms. It may indicate that women who experience vaginal discharge (mucosy, bloody or watery loss) become more nervous and/or excited about labour onset and therefore also often indicate emotional symptoms such as sleep disturbance and emotional unrest. Especially, mucosy show may cause excitement and/or anxiety in primiparas, even more so bloody show or watery loss (e.g. SROM) as a clinical indication of labour onset [3,5,30]. All of these indications can be understood as the physiological basis of the transition into early labour.

The transition into early labour has been described to be characterised by several labour onset symptoms within four days before birth (8). During this transition, primiparas need to decide when it is time to seek professional care, which usually happens when labour starts subjectively. After a time of experiencing other possible symptoms (e.g. irregular pain, vaginal loss and gastrointestinal symptoms), the appearance of regular pain caused primiparas to express a self-diagnosed labour onset. This mirrors midwifery knowledge and the advice given to women in antenatal classes to expect a labour onset once regular pain is starting. As per definition, regular pain marks the beginning of labour [5]. It seems to be something like redemption, implying what has been obvious, and indicating a self-diagnosed labour onset as a resolution. These results may also be interpreted as a 'magnifying glass' to a small group of primiparas that were still rather insecure and uninformed to identify other labour onset symptoms next to regular pain.

Moreover, our data open a bigger window into the past and show the different levels of certainty throughout the primiparas transition into early labour, which starts as early as 32 days before birth [8]. The more certain primiparas were to be in labour, the less time they spent filling in the questionnaire. Being "not sure" of labour onset was seen as another important factor in the transition into early labour. Primiparas indicated

not being sure of a labour onset up until the day of birth, showcasing a special need for primiparas to be reassured and educated about labour onset. This small but enthusiastic sample of primiparas, who filled in the questionnaire daily until either labour onset was certain or the baby was born, can be seen as an exemplary group that deserves further investigation in subsequent research on labour onset. A diary-based questionnaire may be a helpful tool for this purpose.

Primiparas must be seen as a unique group of gravidae who have never experienced birth before. That makes them especially vulnerable to birth-related insecurities and fear [7,11,31]. Qualitative studies have shown that primiparas need appropriate maternity care services according to individual needs, want to be listened to when labour starts and need reassurance that symptoms and signs of early labour are normal [14,32]. Experiencing regular pain at the end of pregnancy can reassure primiparas about normality and, since our study indicated self-diagnosed labour onset to much more likely occur in women with regular pain within the next 24 h than those without, it may be a good indicator to call for professional help. Our study showed some positive association between a self-diagnosed labour onset and lower maternal BMI, newborn sex being female and being born post-date. Although these findings were not statistically significant due to the small sample stemming from having only a 33.8 % response rate, they may be interpreted as a sign of possible indicators towards self-prediction of labour onset. A prospective study with a larger sample could reveal stronger associations and potentially direct midwifery care towards a more woman-centred and needs-oriented care for primiparas in the transition into early labour.

Strengths and limitations

To our knowledge, this is the first study that documented prospective labour onset data from primiparas daily with exact time documentaries. The questionnaire was distributed in German and needed to be filled in continuously from 37 + 0 weeks gestation, which hindered illiterate people and non-German speakers from participating in this study. Moreover, filling in a questionnaire in the last days before and after birth could be challenging for primiparas. However, we can report that the respondents were willing to participate and fill in the study questionnaire continuously for up to 35 days before self-diagnosed labour onset, demonstrating the feasibility of the method. The participation was active also after the women gave birth. Unfortunately, it was not possible to systematically reach all members of the target population in the region due to the SARS-COV-2 pandemic, as personal contacts were restricted and online antenatal classes were not yet established or offered. Therefore, a convenience sample was chosen. Furthermore, the questionnaire was tested for usability but was non-validated prior to conducting this exploratory study. A clear recommendation was not given to document the type of care needed and when to fill in the questionnaire after birth. The pandemic may also have negatively influenced the decision to enter professional care overall and may have indirectly influenced the self-diagnosis of labour onset due to admission restrictions in Germany. The interpretation of these results can only show possible tendencies. Although the external validity of the study was low, it gives valuable insight into this under-researched area of intrapartum care and experience.

The present study is part of a prospective exploratory cohort study (8), and the sample size calculations were conducted to capture the exploratory purpose of the study. Due to the COVID-19 pandemic and time/financial limitations, it was aimed to distribute not less than 150 printed questionnaires with a stamped return envelope to eligible participants only. Therefore, the multivariable binary logistic regression was purely exploratory since the analysis dataset was not based on sample size calculation containing the necessary parameters to develop a model, as highly recommended [33]. In addition, the core assumptions of the regression analysis, linearity and additivity, were not assessed [34]. Such an assessment is crucial when regression analysis is conducted for prediction, inference and testing, as it determines the credibility of the results [34].

The association between self-diagnosed labour onset and regular pain was statistically significant as the 95 % confidence interval did not include the null value (i.e., the odds ratio of 1); however, the estimated odds ratio was very large (at 10.18) and was accompanied by a wide 95 % confidence interval. The large odds ratio may not necessarily reflect clinical significance because it is obtained using a small sample, where larger effects are typical in small studies. Furthermore, the wide 95 % confidence interval reflects great uncertainty in estimating this odds ratio, resulting from having a small sample. A larger study is needed to validate whether this large association is plausible.

Conclusion

Little is known about the definition of the onset of labour from the women's perspective. However, primiparas seem to be able to self-diagnose their labour onset, especially when experiencing regular pain following irregular pain. However, being the initiator of intrapartum care on the one hand but inexperienced of birth on the other, primiparas are a vulnerable group which may enter professional care too late or too early. Our study revealed that regular pain may signal primiparas to self-diagnose labour onset within 24 hrs and uncover other early labour symptoms that may be relevant for a self-diagnosed labour onset. Therefore, antenatal classes, early labour care and woman-centred care should be offered at home or close to birth units based on primiparas needs. Midwives should support individual care needs and shared decision-making when determining the onset of labour for primiparas.

CRediT authorship contribution statement

Hanna Gehling: Writing – review & editing, Writing – original draft, Project administration, Investigation, Formal analysis, Data curation, Conceptualization. **Loukia M. Spineli:** Writing – review & editing, Visualization, Supervision, Formal analysis, Conceptualization. **Mechthild M. Gross:** Writing – review & editing, Supervision, Conceptualization.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Hanna Gehling reports financial support was provided by Hebammengemeinschaftshilfe (DHV). If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgements

We would like to thank all women and midwives who supported this study with their participation. We would also like to thank Suniva Portz (Midwife, PhD student) and Tamara Maraffa (Midwife, PhD student) for her valuable insights during the discussions of the paper. We would also like to thank the financial supporter Hebammengemeinschaftshilfe (HGH) of the German Midwife Association (DHV).

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.srhc.2024.101033.

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