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Antenatal cardiotocography in dutch primary midwife-led care: Maternal and perinatal outcomes and serious adverse events. A prospective observational cohort study

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ABSTRACT

Problem: It is yet unknown whether shifting antenatal cardiotocography (aCTG) from obstetrician-led to midwife-led care leads to a safe reduction in referrals.
Background: ACTG is used to assess fetal well-being. In the Netherlands, the procedure has until now been performed as part of obstetrician-led care. Developments in E-health facilitates the performance of aCTG outside the hospital in midwife-led care, hereby increasing continuity of care.
Aim: To evaluate 1) process outcomes of implementing aCTG for specific indications in primary midwife-led care; 2) maternal and perinatal outcomes of pregnant women receiving aCTG in midwife-led care; 3) serious adverse events (with outcomes, causes, avoidability, and potential prevention strategies) that have occurred during the innovation project 'aCTG in midwife-led care'.
Methods: Prospective observational cohort study and a case series study of serious adverse events.
Findings: A total of 1584 pregnant women with a specific aCTG indication were included in this cohort study for whom 1795 aCTGs were performed in midwife-led care. 1591 aCTGs(89.7%) were classified as reassuring. Referral to obstetrician-led care occurred for 234 women(13.0%) after an aCTG in midwife-led care of whom 202 (86%) were referred back. Severe neonatal morbidity occurred in 27 neonates (1.7%). In the 5736 aCTGs included in the case series study, one case with a serious neonatal outcome was assessed as a serious adverse event attributable to human factors.
Discussion: ACTGs performed in midwife-led care increased continuity of care. In this innovation project, maternal and perinatal outcomes were in the expected range for women in midwife-led care.

Statement of significance

Problem

Shifting antenatal cardiotocography (aCTG) to assess fetal well-being from obstetrician-led to midwife-led care is accompanied by restructuring tasks and responsibilities, and requires evaluation of the quality of care.

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What is Already Known

Women who had an aCTG in midwife-led care are highly satisfied with receiving this care.

What this Paper Adds

Evidence that continuity of care improved for most women who had an aCTG in midwife-led care, without compromising the quality of care, as the maternal and perinatal outcomes were in the expected range for women in midwife-led care.

Introduction

Internationally, maternity care is organised in various ways within healthcare systems. Organising care based on value-based healthcare (VBHC) principles has gained momentum both nationally and internationally [1]. VBHC is a system that prioritises persons' health goals in care decisions and quality improvement, with optimal use of resources (money, time, carbon, and space) [2]. To achieve high-value healthcare, healthcare organisations should be organised as complex adaptive systems centred around persons' needs rather than around separate levels of care [2].

The Dutch maternity care system is divided into primary low-risk midwife-led care (MLC) and secondary high-risk obstetrician-led care (OLC) [3]. Hereby recognising that women eligible for MLC sometimes do have risk factors for poor perinatal outcome, but that risk is being assessed and managed in MLC. Women are referred from MLC to OLC for actual or suspected complications or risk factors that need to be managed in OLC. If no abnormalities are found, the obstetrician in OLC will refer the woman back to MLC, where she continues her care. Continuity of care improves quality of care and contributes to positive pregnancy and childbirth experiences [4–6]. Previous studies have shown that pregnant women in the Netherlands in MLC receive more continuity of care than women referred to OLC, possibly due to the smaller number of healthcare professionals involved in MLC [7]. The women who are referred see new healthcare professionals and hence perceive a discontinuity of care because of the dichotomous healthcare system.

Over recent decades, the number of referrals in the Netherlands from MLC to OLC has increased [8]. Continuity of care in pregnancy and childbirth may be improved by providing more services in MLC, thereby reducing referrals [9,10].

A candidate procedure for this shift is antenatal cardiotocography (aCTG) in situations in pregnancy that pose an increased risk to fetal health, including reduced fetal movements, after external cephalic version performed in primary care and postdate pregnancy. Although there is no clear evidence that aCTG improves perinatal outcomes [11], guidelines widely recommend using aCTG in assessing fetal well-being during pregnancy in women at increased risk of complications [12–15].

ACTG has in the past only been carried out in the hospital by a professional in OLC. Developments in E-health facilitate MLC-aCTG, as the aCTG recording can be assessed in real-time by a second professional who is not present at the location where the aCTG is being performed [3,16]. In three regions in the Netherlands, MLC-aCTG has been implemented for women with the abovementioned indications. In any restructuring of tasks and responsibilities, it is essential to evaluate the quality of care according to VBHC principles, i.e. outcomes measured by important parameters: patient-reported outcome and experience measures along with process and clinical parameters. Research showed that women are highly satisfied with receiving MLC-aCTG [17]. For further implementation, research into the process and health outcomes of women who receive aCTG in the primary care setting and their babies is needed. This study therefore aimed to evaluate: 1) process outcomes of the implementation of MLC-aCTG; 2) maternal- and perinatal outcomes of women receiving MLC-aCTG; 3) the incidence, outcomes, causes, and avoidability of serious adverse events (SAEs) attributable to the use of MLC-aCTG and potential prevention strategies for them.

Materials and methods

Study design

This study comprised an evaluation of an ongoing innovation project, 'MLC-aCTG in three regions in the Netherlands in which women consented for MLC-aCTG. We performed a prospective observational cohort study and a case series study of SAEs. The women included in the cohort study were provided with written and verbal information about the study's aim, and gave their written consent for information to be obtained from their perinatal records. For the case series study, the women included gave their informed consent to participate in the aCTG-innovation project; only pseudonymised data were used for this part.

Setting and procedure

In the Netherlands, risk selection and role division between the MLC and OLC is based on the obstetric indication-list. This document designates the appropriate level of care for over 100 obstetrical conditions [3]. One important aim of this model is to ensure safe midwife-led care for healthy women by performing risk selection. The CTG, a continuous electronic recording of the fetal heart rate, is obtained through an ultrasound transducer placed on the mother's abdomen, and a second transducer to record the presence of any uterine activity. The maternal pulse is monitored via a finger probe. The fetal heart rate, maternal pulse, and uterine activity are monitored simultaneously. According to the obstetric indication-list, when an aCTG is indicated for a pregnant woman in MLC, the primary care midwife refers the woman to OLC for consultation. The woman receives an OLC-aCTG and ultrasound scan in the hospital, usually performed and assessed by a hospital-based midwife or resident under the supervision of an obstetrician. Blood pressure is measured as well. If all findings of CTG, ultrasound, and blood pressure are normal, the obstetrician will refer the woman back to MLC, where her antenatal care will continue. In case of increased risk or of complications, the care is continued in OLC (transfer of care). The innovation project, aCTG in MLC, was implemented in three regions in the Netherlands and started in 2015. ACTGs were performed for healthy pregnant women between 28 and 42 weeks with situations in pregnancy that pose an increased risk, including fetal movements, after external cephalic version in primary care and postdate pregnancy (from 41 +0 weeks). A trained midwife performed the external cephalic version in primary care according to a national standard [18]. The pregnant women were offered the option of an MLC-aCTG or OLC-aCTG. If they opted for MLC, the aCTG was autonomously performed and assessed by a primary care midwife. Another primary care midwife performed a real-time second assessment. Midwives are authorised to perform aCTG provided they are competent in training and experience [19,20]. All primary care midwives who participated in this innovation project followed training on aCTG-assessment completed with an exam. In addition, mandatory attendance of at least four peer-training sessions, where midwives interpret and evaluate aCTGs with each other, together with a consulting obstetrician, was required.

A portable CTG system (Sense4baby®) was used for carrying out aCTGs at women's homes, midwifery practices, or community-based ultrasound centres. ACTG traces with a duration of at least 30 up to 45 min with a paper speed of 2 cm/min were assessed by using a classification system based on the International Federation of Gynecology and Obstetrics (FIGO) guidelines (Fig. 1) [21]. Although the FIGO classification is developed for intrapartum CTG, the Dutch Federation of Obstetrics and Gynaecology recommends using it for aCTG as well [22]. ACTGs could be classified as either reassuring or non-reassuring [11,22–24] or as 'insufficient quality (technical or registration quality)'. In the case of a reassuring aCTG in MLC, within 24 h, an ultrasound scan

Antenatal CTG classification				
CTG classification	**Baseline Heart Frequency (bpm)**	**Accelerations and variability**	**Decelerations**	**Contractions**
Reassuring: The CTG complies with *all* criteria	110-150	Minimal two accelerations in a 45-minute CTG tracing Variability 5-25 bpm	Absence of decelerations	Maximum of two contractions per 10 minutes Absence of hypertonia
Non-reassuring: The CTG deviates from *one or more* criteria	<110 or >150	< two accelerations in a 45-minute CTG tracing Variability <5 or > 25 bpm	Presence of 1 or more decelerations	>two contractions per ten minutes. Presence of hypertonia

CTG, cardiotocography; bpm, beats per minute.

Fig. 1. Antenatal CTG classification system used in the study.

was performed in primary care to assess fetal growth, amniotic fluid, and presentation of the fetus. Blood pressure was measured as well. If all findings of aCTG, ultrasound, and blood pressure were normal, antenatal care was continued in MLC.

If an aCTG was classified as non-reassuring or of insufficient quality, the woman was immediately referred to OLC for follow-up. Depending on the level of seriousness and the distance to the nearest hospital, this was by own transport or by ambulance. In each region, a quality committee monitors the quality of aCTG-assessments performed by primary care midwives by structurally evaluating randomly selected aCTG-assessments plus all aCTGs where a serious perinatal outcome such as perinatal death or severe perinatal morbidity with admission to neonatal intensive care unit (NICU), subsequently occurred.

Cohort study

Data collection

The aCTG-innovation project started on January 1, 2015. After a run-in period, the inclusions for the cohort study were obtained from the ongoing project from August 1, 2016, to December 31, 2020. Midwifery practices were approached to obtain medical records of the women who gave consent to collect their data on maternal demographic and anthropometric characteristics, characteristics of the aCTG care process, medical and obstetric history, care during pregnancy, birth characteristics, and the postpartum period. Data were entered in the clinical database system Castor EDC. Prior to data cleaning, including screening data for logical errors and extreme value checks, we evaluated data entry error to ensure the integrity of the captured data. Double data entry was performed for 5% of all medical records and showed 1.19% errors in data entry. Percentages below 3% are considered acceptable; therefore, double-entering all data was not needed [25]. In cases where data were missing, midwives were contacted by the researcher to retrieve the missing data. When no data could be retrieved, women were excluded.

Outcomes

We used the core outcome set for pregnancy and childbirth, proposed by the International Consortium of Health Outcomes Measurements (ICHOM) [26]. The set was supplemented with outcome measures from the core outcome set for evaluating models of maternity care, published by the COMET initiative [27]. The process outcomes were aCTG location, gestational age at the aCTG, the conclusion of the aCTG-assessment, bi-disciplinary discussion (between primary care midwife and obstetrician), referral or transfer of care to OLC and the reason (non-reassuring aCTG: suboptimal aCTG, abnormal aCTG, or aCTG of insufficient quality), ultrasound abnormalities (in fetal growth, amniotic fluid, presentation of the fetus), other (hypertension, uterus contractions, persistently reduced fetal movements, non-cephalic position after external cephalic version in primary care), and the total number of aCTGs in primary care. Maternal outcomes were level of care at the onset of labour, level of care at birth, place of birth, mode of birth (spontaneous vaginal birth, assisted vaginal birth, planned cesarean section (c-section), c-section during labour for suspected fetal distress or prolonged labour), induction of labour, pharmacological pain relief, perineal trauma, postpartum haemorrhage (PPH) (<1000 mL, 1000–2000 mL, >2000 mL), and maternal death. Perinatal outcomes were Apgar score (AS) < 7 at five minutes, birth weight (small for gestational age (<10th percentile) or large for gestational age (>90th percentile)), shoulder dystocia, consultation of a paediatrician, admission of the neonate, neonatal length of stay (number of consecutive days in the hospital up to seven days after birth), neonatal nutrition (intention, and at seven days postpartum) and a dichotomous composite measure of severe adverse neonatal outcomes occurring up to seven days after birth: AS < 4 at five minutes; perinatal death (after 28 +0 weeks gestation); ventilation with intubation; encephalopathy; meconium aspiration syndrome; brachial plexus injury; infant respiratory distress syndrome (IRDS); pneumothorax; necrotising enterocolitis (NEC); convulsions; sepsis; meningitis; other (additional information in Table S1).

Analyses

The details of the aCTG care process, characteristics and health outcomes of the pregnant women and their newborns from birth to seven days postpartum were analysed with descriptive statistics and presented as frequencies and percentages for categorical variables and means and standard deviations for continuous variables. The categories for the ethnic background were not filled in uniformly by midwives and were therefore unreliable. We therefore classified ethnicity as 'Dutch' or 'non-Dutch.' Socioeconomic status (SES) was based on the mean household income level of the respondent's neighbourhood, as determined by the first four digits of the women's postal codes. We stratified the results by the three aCTG indications. Missing data are presented in the Tables. Analyses were conducted using the Statistical Package for Social Sciences (SPSS) version 26.0 for Windows (SPSS Inc., Chicago, IL, USA).

Case series study

Data collection

To be transparent and as complete as possible about the safety of aCTG in MLC, we investigated potential serious adverse events in all women who received an MLC-aCTG during the aCTG-innovation project from January 1, 2015 to December 31, 2020. Women who agreed to have an MLC-aCTG consented to the regional quality committees to collect data for cases with a potential SAE to evaluate whether the SAE was attributable to the aCTG-innovation project. We developed an online case record form (CRF) in Castor EDC for in-depth anonymous

information about the potential SAEs. A link to the CRF was sent by e-mail to the involved healthcare professional. We asked for details about the pregnancy, the situation where the potential SAE had occurred, the circumstances, and the procedure that followed. All cases were reported anonymously, and references to the identity of the healthcare professional and the hospital were deleted before analysis.

Outcomes

A potential SAE was described as a perinatal death or severe perinatal morbidity defined as admission of the neonate to NICU after an aCTG was performed in MLC.

Analyses

We created an overview of cases of perinatal death or severe perinatal morbidity during the indicated time period in the three regions. All cases were assessed by an expert team consisting of a midwife with an educational background in aCTG, a hospital-based midwife, and an obstetrician with experience in perinatal auditing and assessing incidents of sub-standard care. All three had expertise in assessing aCTGs and were not involved in the innovation project. A standardised procedure with a structured assessment was used to assess each potential SAE. The team was informed about the aCTG setting, procedure, and regional quality protocol regarding aCTG in primary care. For each case, the assessment consisted of three phases according to the 'Eindhoven classification model-Prisma method' and the KNOV-guideline 'Dealing with calamities in midwifery practices' [28,29].

Assessment Phase 1: determine SAEs caused by clinical management in MLC. The expert team screened the records in the first assessment phase using 18 explicit screening criteria indicating potential SAEs. The records that met the screening criteria were reviewed and discussed to reach consensus on whether an SAE was related to clinical management in MLC. This decision was based on three criteria: 1) an unintended or unexpected event involving serious physical injury for the neonate, 2) the event resulted in temporary or most likely permanent disability, death, or NICU admission, and 3) the event was caused by clinical management of the care professional [30]. The degree to which the potential SAE caused by clinical management was measured using a 6-point scale (one=not caused by clinical management, and six=clearly caused by clinical management). As in other studies, a score of one to three indicated that the case was not an SAE caused by clinical management in MLC, and a score of four or higher indicated an SAE caused by clinical management in MLC [31].

Assessment Phase 2: classifying the causes of SAEs. In the second assessment phase, each SAE caused by clinical management was assessed by each expert independently using an assessment form to determine how the SAE could have happened and what might have caused it. SAEs often arise from multiple causal factors, such as human, organisational, technical, and patient-related factors. The experts selected all factors contributing to the SAE (Fig. 2).

A plenary discussion to reach consensus followed each expert's independent assessment. If consensus could not be reached, a majority decision was used.

Assessment Phase 3: Classification of avoidability and prevention strategies. In the third assessment phase, the expert team assessed whether the SAEs were avoidable and, if so, potential prevention strategies were selected. Avoidability was defined as care below the professional standard and expected performance of professionals and systems. Avoidability was classified using a 6-point scale (one=not avoidable and six=clearly avoidable). As in other studies, a score of one to three indicated that the SAE was not avoidable, and a score of four or higher indicated that the SAE was avoidable [31]. The assessment form distinguished eleven prevention strategies: peer review, training, evaluation, procedures, motivation, information, communication, technique/equipment, personal, scaling, and financial investment. The experts could select one or more prevention strategies for each SAE.

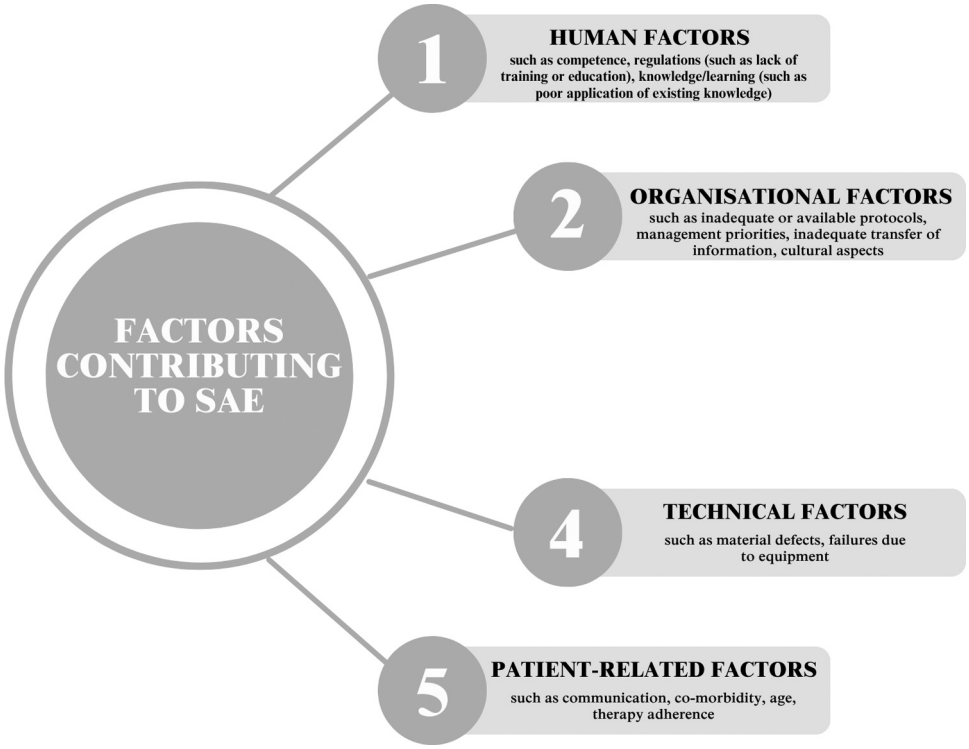

Fig. 2. Causal factors of SAEs.

Results

Cohort study

During the five-year study period, 1628 women gave informed consent to having their data included in the prospective cohort study. No data could be retrieved for 31 women. In 13 women (0.8%), the aCTG was performed in OLC. These women (n = 44) were excluded from further analyses (Fig. 3).

Case series study

Throughout the duration of the project (six years), in the three regions, 5736 MLC-aCTGs were performed. Seven potentially serious adverse events cases were retrospectively selected over these years and included in the case series study (Fig. 3).

Maternal demographic and anthropometric characteristics

In total, 1584 pregnant women were included in the cohort study in whom 1795 MLC-aCTGs were performed. The baseline characteristics are presented in Table 1. The mean age was 31.1 years, and most women were nulliparous (n = 959, 60.5%), between 20 and 36 years old (n = 1347, 85.2%) and Dutch (n = 612, 68.6%). The mean gestational age at birth was 40 + 1 weeks.

CTG care process characteristics

Table 2 shows the characteristics of the aCTG care process. Most aCTGs (n = 1459, 81.3%) were performed at the woman's midwifery practice, whereas 308 aCTGs (17.2%) were performed in a community ultrasound centre and 28 aCTGs (1.6%) at the woman's home. Overall, 1591 aCTGs (89.7%) were reassuring, meaning that these women did not need to be referred to the hospital where they usually would have received the aCTG. A referral to secondary care was indicated after 234 CTGs (13.0%); 9.6% due to non-reassuring aCTG (including aCTGs of insufficient quality), ultrasound abnormalities (3.3%), or other reasons (0.7%). Of these women, 86.3% (202/234) were referred back to MLC. The care for the other 32 women (13.7%, 32/234) was transferred to OLC. Reasons for transfer of care were non-reassuring aCTG (including aCTGs of insufficient quality) (31.3%, 10/32), ultrasound abnormalities (71.9%, 23/32), or other reasons (9.4%, 3/32). Some women received multiple aCTGs for one or more aCTG indications in MLC during pregnancy; 180 women had two CTGs (11.4%), 43 women had three aCTGs (2.7%), five women had four aCTGs (0.3%), and one woman had five aCTGs (0.1%).

Maternal and neonatal outcomes

Of the women who received an MLC-aCTG, 1088 (68.9%) were in MLC at the onset of labour, and 498 women (31.5%) gave birth in MLC with 228 (14.4%) giving birth at home (Table 3). Of all women, 1218 (77.2%) had a spontaneous vaginal birth, 145 (9.2%) had an assisted vaginal birth, and 216 (13.6%) had a c-section. For 78 women (4.9%), a planned c-section was carried out, mostly in the group with the indication 'external cephalic version' (n = 65, 26.2%). During labour, 138 (8.7%) women had a c-section, 4.8% for suspected fetal distress, and 3.9% for prolonged labour. In 371 women (24.7%), labour was induced. Most women gave birth without pharmacological pain relief (n = 850, 56.5%) and had first or second-degree tear (n = 735, 54.2%). Twenty-four neonates (1.5%) had Apgar scores below seven at five minutes postpartum. One hundred and forty-eight neonates (9.6%) were born with a birth weight below the 10th percentile (SGA) and 121 (7.8%) above the 90th percentile (LGA). Thirty-three neonates (2.1%) were born pre-term (<37 weeks gestation). For 564 neonates (35.8%), the paediatrician was consulted within the first 12 h postpartum, and 181 neonates (11.5%) were admitted to the pediatric ward or NICU within the first seven days postpartum. During the 6-year study period, 27 neonates (1.7%) experienced one or more severe neonatal outcomes. Four cases (0.3%) of perinatal death (up to 28 days after birth), were reported. The causes were asphyxia, Potter's sequence, and tight umbilical cord entanglement, respectively. For one case, the cause of death was unknown. An overview of the most relevant clinical diagnoses of the composite severe neonatal outcome is given in Supplementary Table S1.

Severe adverse event case selection

During the total innovation project, 5736 MLC-aCTGs were performed. Seven cases (0.1%) with a potential SAE were retrospectively reported. Table 4 provides an overview of the potential SAEs with a case description, whether it was attributable to the aCTG-innovation project, and, if applicable, the causes of an SAE. After a critical incident analysis by the multidisciplinary expert team, five potential SAEs were excluded from further analysis because of a causality score of zero (no evidence of being related to clinical management). One case was assessed with a causality score of three (causality with clinical management not likely,

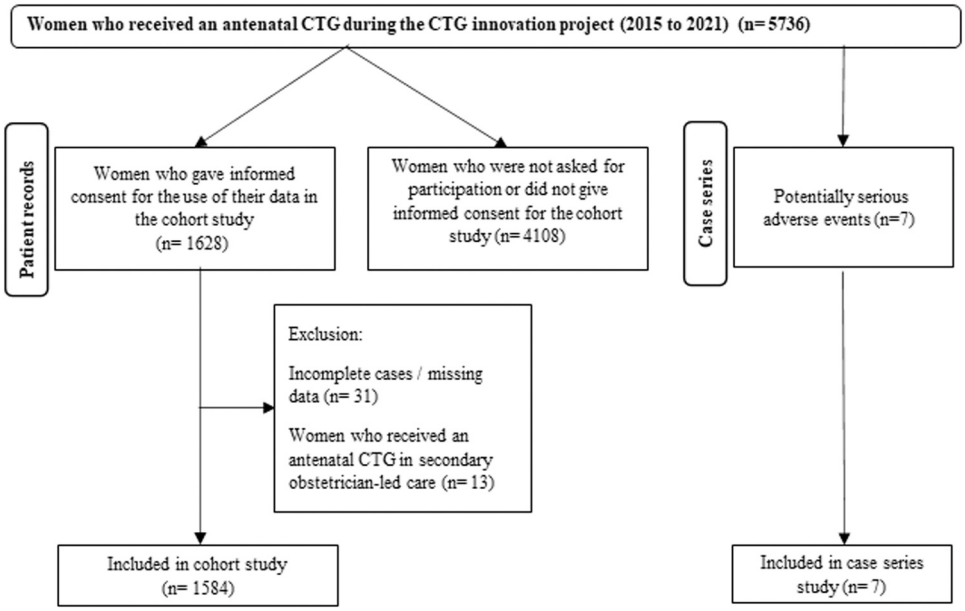

Fig. 3. Flowchart of the study population.

Table 1
Maternal demographic and anthropometric characteristics of all women and per indication for antenatal CTG.

	Total women n = 1584 (%)	Total aCTGs[a] n = 1795		
		Reduced fetal movements n = 1211 (%)	External cephalic version n = 249 (%)	Postdate pregnancy n = 335 (%)
Maternal age (years), mean (SD)	31.1 (4.6)	30.6 (4.7)	31.9 (4.1)	32.3 (4.3)
missing	*3*	*3*	*0*	*0*
Maternal age (years)				
<20	18 (1.1)	24 (2.0)	0 (0.0)	0 (0.0)
20–36	1347 (85.2)	1047 (86.7)	207 (83.1)	268 (80.0)
> 36	216 (13.7)	137 (11.3)	42 (16.9)	67 (20.0)
missing	*3*	*3*	*0*	*0*
Parity				
Nulliparous	959 (60.5)	721 (59.5)	173 (69.5)	199 (59.4)
Multiparous	625 (39.5)	490 (40.5)	76 (30.5)	136 (40.6)
BMI				
<18,5	35 (2.2)	28 (2.3)	9 (3.6)	7 (2.1)
18,5–25	966 (61.4)	682 (56.8)	168 (67.8)	225 (67.4)
>25	572 (36.4)	491 (40.9)	71 (28.6)	102 (30.5)
missing	*11*	*10*	*1*	*1*
Ethnicity				
Dutch	612 (68.6)	395 (61.6)	128 (85.9)	183 (80.3)
Non-Dutch	280 (31.4)	246 (38.4)	21 (14.1)	45 (19.7)
Missing	*692*	*570*	*100*	*107*
SES				
High	381 (24.1)	286 (23.7)	74 (29.7)	75 (22.6)
Medium	687 (43.5)	537 (44.4)	115 (46.2)	125 (37.7)
Low	511 (32.4)	386 (31.9)	60 (24.1)	132 (39.7)
Missing	*5*	*2*	*0*	*3*
Gestational age at birth (weeks) mean (SD)	(40+1) (1.3)	40+0 (1.3)	39+5 (1.2)	41+4 (0.3)
missing	*6*	*4*	*2*	*0*

aCTG=antenatal cardiotocography [a]The total number of CTGs is higher than the total number of pregnant women due to 11.1% of the pregnant women having>1 CTG in primary midwife-led care. BMI: body mass index

but a close call). The experts identified one SAE related to human factors, i.e., incorrect aCTG-assessment and subsequent fetal death (causality score of six; clear evidence for causality with clinical management). The experts judged the SAE to be avoidable (avoidability score of six: clear evidence for avoidability). In consequence of the critical incident analysis, the experts recommended two potential prevention strategies for this SAE: ensuring sufficient exposure in assessing aCTGs, and considering only performing MLC-aCTGs from 32 weeks onwards. Furthermore, they underlined the importance of performing MLC-aCTG-assessment by two professionals and aCTG training to improve competence.

Discussion

Key results

This study evaluated an innovation project of aCTG in MLC. In the cohort study of 1795 aCTGs, 89.7% of the aCTGs were classified as reassuring, meaning that these women did not need to be referred to the hospital where they normally would have received the CTG. Referral to OLC after an MLC-aCTG occurred for 234 women (13.0%), of whom 86.3% (202/234) were referred back. In the total innovation project, the expert group assessed one case of a serious perinatal outcome as an SAE attributable to human factors. Severe neonatal morbidity, defined as a composite measure of severe outcomes, occurred among 1.7% of neonates. Four cases of perinatal death were reported. The causes were asphyxia, Potter's sequence, and tight umbilical cord entanglement. For one case, the cause of death was unknown.

Interpretation

Our findings indicate that the task shift in this innovation project significantly reduces the number of referrals to OLC: only 13.0% of the women were referred. In the traditional care process, all women in MLC with an aCTG indication are referred to OLC. This shows the improvement in continuity of care, contributing to women's satisfaction with care [5–7]. We found that 89.7% of the aCTGs performed by primary care midwives were classified as reassuring. The high rate of reassuring MLC-aCTGs was to be expected due to the healthy population [32]. Saastad et al. investigated 3014 Norwegian pregnant women with reduced fetal movements in whom an aCTG was performed in a hospital setting. They found fetal distress, intrauterine growth restriction, oligohydramnios, or another abnormality in 3.2% of pregnancies [33]. In our study, we found a higher percentage of aCTG and ultrasound abnormalities for pregnant women who received an MLC-aCTG in primary midwife-led care for the indication reduced fetal movements, as our results show 9.6% referral for non-reassuring CTG, 3.3% for ultrasound abnormalities, and 0.7% for another reason. An explanation for this higher percentage in the current study might be that the criteria of an assessment of MLC-aCTG are more strict than in OLC to ensure safety, because performing aCTG in MLC is an innovation, and a first step in the detection of potential fetal hypoxia. In the case series study, midwifery care was evaluated among women with a potential SAE attributable to the aCTG-innovation project. The maternal and perinatal outcomes were in the expected range for women with an indication for aCTG among a previously low-risk population. We compared these results to the Dutch IRIS study [34]. The IRIS study included women at 28 weeks gestation with healthy pregnancies in MLC. This study showed a similar neonatal mortality rate (0.3%) and composite severe neonatal outcome rate (1.7%) during pregnancy for low-risk women. The literature shows that pregnancies in which the mother reports decreased fetal movements are associated with adverse outcomes: stillbirth, fetal growth restriction, and associated conditions [23,35,36]. Our research shows that the number of SGA neonates in the group of mothers who reported reduced fetal movements is 9.6%. This percentage is slightly higher than the incidence rate in a low-risk population of 8.1%, reported in the IRIS study [34]. We could not confirm that reduced fetal movements is associated with stillbirth and adverse severe outcomes. The Cochrane

Table 2
Characteristics of CTG care process presented for CTGs as a whole and for each indication for antenatal CTG.

	Total aCTGs n = 1795 (%)	Reduced fetal movements n = 1211 (%)	External cephalic version n = 249 (%)	Postdate pregnancy n = 335 (%)
Location aCTG				
Woman's own midwifery practice	1459 (81.3)	1133 (93.6)	9 (3.6)	317 (94.6)
Other midwifery practice / community ultrasound centre	308 (17.1)	51 (4.2)	240 (96.4)	17 (5.1)
Woman's home	28 (1.6)	27 (2.2)	0 (0.0)	1 (0.3)
Conclusion aCTG-assessment				
Reassuring CTG	1591 (89.7)	1044 (87.0)	236 (97.5)	311 (94.0)
Non-reassuring CTG	147 (8.3)	122 (10.2)	6 (2.5)	19 (5.7)
Insufficient quality	35 (2.0)	34 (2.8)	0 (0.0)	1 (0.3)
missing	*22*	*11*	*7*	*4*
Conclusion aCTG-assessment per GA				
28+0 – 31+6 weeks	217 (12.3)	217 (18.2)	0 (0.0)	0 (0.0)
Reassuring	177 (10.0)	177 (14.8)	0 (0.0)	0 (0.0)
Non-reassuring	26 (1.5)	26 (2.2)	0 (0.0)	0 (0.0)
Insufficient quality	14 (0.8)	14 (1.2)	0 (0.0)	0 (0.0)
32+0 – 36+6 weeks	573 (32.4)	366 (30.6)	207 (85.9)	0 (0.0)
Reassuring	527 (29.8)	326 (27.3)	201 (83.4)	0 (0.0)
Non-reassuring	40 (2.3)	34 (2.8)	6 (2.5)	0 (0.0)
Insufficient quality	6 (0.3)	6 (0.5)	0 (0.0)	0 (0.0)
37+0 – 40+6 weeks	616 (34.9)	578 (48.4)	34 (14.1)	4 (1.2)
Reassuring	546 (30.9)	508 (42.5)	34 (14.1)	4 (1.2)
Non-reassuring	57 (3.2)	57 (4.8)	0 (0.0)	0 (0.0)
Insufficient quality	13 (0.8)	13 (1.1)	0 (0.0)	0 (0.0)
41+0 – 42+0 weeks	361 (20.4)	34 (2.8)	0 (0.0)	327 (98.8)
Reassuring	335 (18.9)	28 (2.3)	0 (0.0)	307 (92.8)
Non-reassuring	24 (1.4)	5 (0.4)	0 (0.0)	19 (5.7)
Insufficient quality	2 (0.1)	1 (0.1)	0 (0.0)	1 (0.3)
missing	*28*	*16*	*8*	*4*
Bi-disciplinary discussion				
No	1746 (97.3)	1166 (96.3)	248 (99.6)	332 (99.4)
Yes	48 (2.7)	45 (3.7)	1 (0.4)	2 (0.6)
missing	*1*	*0*	*0*	*1*
Referral to obstetrician-led care				
No	1561 (87.0)	1024 (84.6)	231 (92.8)	306 (91.3)
Yes	234 (13.0)	187 (15.4)	18 (7.2)	29 (8.7)
Referred back to midwife-led care	202/234 (86.3)	168/187 (89.8)	9/18 (50.0)	25/29 (86.2)
Transfer of care by obstetrician-led care	32/234 (13.7)	19/187 (10.2)	9/18 (50.0)	4/29 (13.8)
Reason referral to obstetrician-led care[a]				
Non-reassuring aCTG[b]	172/234 (73.5)	147/187 (78.6)	6/18 (33.3)	19/29 (65.5)
Ultrasound abnormalities	60/234 (25.6)	37/187 (19.8)	13/18 (72.2)	10/29 (34.5)
Other[c]	12/234 (5.1)	11/187 (5.9)	0/18 (0.0)	1/29 (3.4)
Reason transfer of care by obstetrician-led care[d]				
Non-reassuring aCTG[b]	10/32 (31.3)	8/19 (42.1)	0/9 (.0)	2/4 (50.0)
Ultrasound abnormalities	23/32 (71.9)	12/19 (63.2)	8/9 (88.9)	3/4 (75.0)
Other[e]	3/32 (9.4)	2/19 (10.5)	1/9 (11.1)	0/4 (0.0)

aCTG = antenatal cardiotocography
[a] Referral to obstetrician-led care may have been for ≥1 reason.
[b] Including CTGs with insufficient quality.
[c] Reasons such as hypertension, uterus contractions, persistently reduced fetal movements.
[d] Transfer of care to obstetrician-led care may have been for ≥1 reason.
[e] Reasons include hypertension, persistently reduced fetal movements, and induction of labour.

review by Grivell et al. assesses the effectiveness of aCTG in improving outcomes for mothers and babies during and after pregnancy [11]. They found no difference in the risk of a c-section for women with an increased risk of complications for the fetus between having an aCTG performed or having no aCTG performed. We can confirm this observation, as we found that c-sections were performed among 13.6% of women, which is similar to the percentage of c-sections among low-risk women reported in the IRIS study (13.6%) [34]. Additionally, van der Pijl et al. reported that primary care midwives believed that an important effect of performing aCTG in primary midwife-led care could be a reduced number of inductions of labour [37]. Unfortunately, it was not possible to make a reliable comparison with national numbers. The findings from this study may support further implementation of value-based healthcare and accelerate the transformation towards personalised care by task shifting. Still, continued governance of quality of care in MLCand OLC remains an important issue.

Generalizability

Our findings are important for maternity care both in the Netherlands and internationally. Although a referral from MLC to OLC in itself is not an adverse perinatal outcome, discontinuity of care (e.g., in cases of referrals to another care professional) could affect the quality of care due to transmission and loss of information [7]. Evaluation of the new situation with aCTGs in MLC using E-health equipment showed a high rate of women who could receive safe care in MLC, which results in more continuity of care. It might be time to reconsider the current strict task division between MLC and OLC and optimise the roles of these professionals to improve continuity of care and access to key maternal and newborn health interventions where accessibility to obstetrician specialists is limited. CTG has well-documented limitations and professionals must understand the potential advantages and disadvantages of the technology before it is offered to women [11]. Poor CTG

Table 3
Maternal and neonatal outcomes presented for all participants and per indication for antenatal CTG.

	Total women n = 1584 (%)	Total aCTGs[a] n = 1795		
		Reduced fetal movements n = 1211 (%)	External cephalic version n = 249 (%)	Postdate pregnancy n = 335 (%)
Level of care at onset of labour				
Midwife-led care	1088 (68.9)	881(73.0)	103 (41.4)	233 (69.6)
Obstetrician-led care	492 (31.1)	326 (27.0)	146 (58.6)	102 (30.4)
missing	*4*	*4*	*0*	*0*
Level of care at birth				
Midwife-led care	498 (31.5)	401 (33.2)	51 (20.5)	95 (28.4)
Obstetrician-led care	1082 (68.5)	806 (66.8)	198 (79.5)	240 (71.6)
missing	*4*	*4*	*0*	*0*
Place of birth				
Midwife-led care				
Home	228 (14.4)	178 (14.7)	20 (8.1)	56 (16.7)
Birth centre	65 (4.1)	60 (5.0)	2 (0.8)	6 (1.8)
Hospital	166 (10.5)	131 (10.9)	23 (9.2)	29 (8.7)
Hospital (medium risk)	39 (2.5)	32 (2.7)	6 (2.4)	4 (1.2)
Obstetrician-led care: hospital	1082 (68.5)	806 (66.7)	198 (79.5)	240 (71.6)
missing	*4*	*4*	*0*	*0*
Mode of birth[b]				
Spontaneous vaginal birth	1218 (77.2)	985 (81.7)	122 (49.2)	260 (77.6)
Assisted vaginal birth	145 (9.2)	109 (9.0)	19 (7.7)	40 (11.9)
Cesarean section planned	78 (4.9)	22 (1.8)	65 (26.2)	0 (0.0)
Cesarean section during labour				
Suspected fetal distress	76 (4.8)	53 (4.4)	28 (11.3)	12 (3.6)
Prolonged labour	62 (3.9)	38 (3.1)	14 (5.6)	23 (6.9)
missing	*5*	*4*	*1*	*0*
Induction of labour[c]				
No	1130 (75.3)	895 (75.5)	140 (76.5)	226 (67.5)
Yes	371 (24.7)	290 (24.5)	43 (23.5)	109 (32.5)
missing	*83*	*26*	*66*	*0*
Pharmacological pain relief[c]				
No	850 (56.5)	656 (55.4)	115 (62.8)	185 (55.2)
Yes, epidural	484 (32.2)	379 (31.9)	56 (30.6)	123 (36.7)
Yes, remifentanil	207 (13.8)	180 (15.2)	16 (8.7)	36 (10.7)
Yes, other				
Relivopan	21 (1.4)	21 (1.8)	0 (0.0)	2 (0.6)
Pethidine	17 (1.1)	16 (1.3)	2 (1.1)	3 (0.9)
missing	*80*	*23*	*66*	*0*
Perineal trauma[d]				
No, intact perineum	257 (18.9)	217 (19.9)	25 (17.9)	45 (15.1)
Yes, first or second-degree tear	735 (54.2)	602 (55.3)	61 (43.6)	160 (53.7)
Yes, third or fourth-degree tear	66 (4.9)	49 (4.5)	9 (6.4)	18 (6.0)
Yes, episiotomy	313 (23.1)	229 (21.0)	48 (34.3)	80 (26.8)
missing	*227*	*122*	*109*	*37*
Postpartum haemorrhage				
<1000 mL	1434 (90.5)	1104 (91.2)	232 (93.2)	285 (85.1)
1000–2000 mL	125 (7.9)	88 (7.3)	15 (6.0)	41 (12.2)
>2000 mL	25 (1.6)	19 (1.6)	2 (0.8)	9 (2.7)
Maternal death				
No	1583 (100.0)	1210 (100.0)	249 (100.0)	335 (100.0)
Yes	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
missing	*1*	*1*	*0*	*0*
Pre-term birth (<37 weeks)				
No	1547 (97.9)	1178 (97.6)	243 (98.4)	335 (100.0)
Yes	33 (2.1)	29 (2.4)	4 (1.6)	0 (0.0)
missing	*4*	*4*	*2*	*0*
Shoulder dystocia				
No	1577 (99.6)	1208 (99.8)	249 (100)	331 (98.8)
Yes	7 (0.4)	3 (0.2)	0 (0.0)	4 (1.2)
Apgar score <7 at five minutes				
No	1560 (98.5)	1193 (98.5)	243 (97.6)	333 (99.4)
Yes	24 (1.5)	18 (1.5)	6 (2.4)	2 (0.6)
Composite severe neonatal outcome[e]				
No	1557 (98.3)	1190 (98.3)	246 (98.8)	331 (98.9)
Yes	27 (1.7)	21 (1.7)	3 (1.2)	4 (1.2)
Birthweight[f]				
<10th percentile (SGA)	148 (9.6)	114 (9.5)	31 (12.6)	26 (8.7)
10th-90th percentile	1273 (82.6)	995 (82.9)	197 (80.1)	250 (83.6)
>90th percentile (LGA)	121 (7.8)	91 (7.6)	18 (7.3)	23 (7.7)
missing	*42*	*11*	*3*	*36*
Consultation paediatrician				
No	829 (52.7)	695 (57.6)	84 (34.3)	157 (47.2)
Yes, ≤12 h postpartum	564 (35.8)	377 (31.2)	138 (56.3)	130 (39.0)

(*continued on next page*)

Table 3 (*continued*)

	Total women n = 1584 (%)	Total aCTGs[a] n = 1795		
		Reduced fetal movements n = 1211 (%)	External cephalic version n = 249 (%)	Postdate pregnancy n = 335 (%)
Yes, and admission of neonate (pediatric ward or NICU) ≤7 days postpartum	181 (11.5)	135 (11.2)	23 (9.4)	46 (13.8)
missing	*10*	*4*	*4*	*2*
Neonate length of stay (days), mean (SD)	2.5 (3.2)	2.6 (3.5)	2.6 (3.2)	2.1 (1.8)
missing	*998*	*803*	*109*	*210*
Neonatal nutrition				
Intention (at one day postpartum)				
Breastfeeding	1210 (80.2)	892 (78.0)	189 (78.8)	283 (85.5)
Formula	298 (19.8)	251 (22.0)	51 (21.3)	48 (14.5)
missing	*76*	*68*	*9*	*4*
At seven days postpartum				
Breastfeeding	1107 (75.8)	797 (72.6)	187 (77.6)	269 (83.0)
Formula	354 (24.2)	301 (27.4)	54 (22.4)	55 (17.0)
missing	*123*	*113*	*8*	*11*

aCTG=antenatal cardiotocography; NA=not applicable; SGA=small for gestational age (birth weight <10th percentile of the Dutch (Perined) birth weight curve); LGA=large for gestational age (birth weight >90th percentile of the Dutch (Perined) birth weight curve).

[a] The total number of aCTGs is higher than the total number of pregnant women due to 11.1% of the pregnant/

[b] If cesarean section during labour after failed vacuum-assisted birth, coded as cesarean section during labour by non-progression.

[c] Outcome 'cesarean section planned 'excluded from analysis. 5.3% of women have received multiple types of pharmacological pain relief.

[d] outcome 'cesarean section' excluded from analysis. 1.1% of women had episiotomy and a third or fourth-degree perineal trauma.

[e] Composite outcome: AS < 4 at five minutes, perinatal death (up to 28 days postpartum), ventilation with intubation, encephalopathy, meconium aspiration syndrome, brachial plexus injury, IRDS, NEC, convulsions, sepsis, meningitis).

[f] Birthweight expressed in percentiles Dutch Perined birthweight curve (Hoftiezer).

interpretation, limited knowledge of the pathophysiology of fetal oxygenation, and inadequate clinical management may result in either unnecessary or too little obstetric interventions, with additional risk for both mother and newborn [21]. It is recognised that clinical guidelines need to be as simple and objective as possible if implementation is to be consistent, to allow rapid decision-making even in complex and stressful situations [21]. In addition, it seems sensible to organise regular and structured integrated training of health professionals in MLC and OLC to ensure proper use of technology.

The expert team recommended performing MLC-aCTGs only closer to term (for example, from 32 weeks instead of 28 weeks gestation) because of the difficulty of the assessment of aCTGs at lower gestations. While this consideration may sound plausible, this was based on only one case and merits further research. Research on the quality of aCTG assessment should be evaluated with some urgency and should focus on the benefit of aCTG for specific indications, inter- and intraobserver agreement in aCTG-assessment between professionals in MLC en OLC, and the use of computerised aCTG, to establish whether these strategies add value to the quality of maternity care.

Strengths and limitations

To our knowledge, this is the first prospective cohort study on MLC-aCTG. A strong aspect of this study is the large number of aCTGs (5736) performed in MLC. Our approach of combining descriptive data with an in-depth case series study gives a complete and transparent insight into the care process in MLC. Our study has some limitations. We did not collect data on process outcomes, maternal and perinatal outcomes, or SAEs among healthy pregnant women who received an OLC-aCTG. For this reason, it was impossible to compare maternal- and perinatal outcomes when shifting aCTG to MLC. The same applies to the critical incident analysis among SAEs: we did not evaluate the care in OLC in the reported cases. We could therefore not investigate potential cases of suboptimal care associated with aCTGs in OLC. Another limitation is that potential SAEs were collected retrospectively by each regional quality committee, which engenders the risk of recall bias. For this reason, the incidence of SAEs in our study may be an underestimation. However, we expect this effect to be small as the respondents were all members of the regional quality committees to which all cases with a serious outcome should be reported and discussed. Lastly, not all eligible women were invited to participate in the cohort study as this evaluation was initiated after a run-in period when the pilot started. Furthermore, some midwives did not include women during the inclusion period due to logistical problems, lack of time, or emergencies. This means selection bias of the study population within the cohort study cannot be excluded, and this may have impacted the results. However, it is unlikely that there was a systematic bias in the women included in the study. All women with a potential SAE were taken from the total population, and the number of these cases was therefore likely to be complete.

Conclusion

Our prospective cohort study showed that continuity of care improved for most women who received MLC-aCTG if indicated. Data about the Maternal and perinatal outcomes of women who had an MLC-aCTG were in the expected range for women in MLC. However, to evaluate rare outcomes a larger sample size would be required. The findings from this study may support further implementation of value-based healthcare and accelerate the transformation towards personalised care by task shifting. Still, continued governance of quality of care in MLC and OLC remains an important issue.

Ethical approval statement

Ethical approval was requested from the Medical Ethics Committee of VU University Medical Centre. They deemed the Medical Research Involving Human Subjects Act not to be applicable to our study (VUmc MEC, #2016.484).

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Table 4
Case descriptions of (potential) serious adverse events after antenatal CTG in midwife-led care.

Total aCTGs n = 5736							
Case no.	**Outcome**	**Case description**	**aCTG SAEs (causality score 4–6)**	**Cause SAE**			
				Human factors	*Organisational factors*	*Patient-related factors*	*Other factors*
1	Stillbirth	Indication for aCTG: Reduced fetal movements. GA: 31 + 0. Conclusion of primary care midwife: normal aCTG, normal ultrasound, normal blood pressure. Care management: regular care. Follow-up: After a few days, extra consultation because of pre-eclampsia symptoms. Fetal death diagnosed.	Yes (score 6)	Incorrect aCTG-assessment.			
2	Stillbirth	Indication for aCTG: Reduced fetal movements. GA: 37 + 6. Conclusion of primary care midwife: suboptimal aCTG. Care management: Immediate referral to secondary care. Follow up: 30 min later, aCTG/ultrasound in secondary care bradycardia and emergency cesarean section followed. AS 0/0, 3240 g. 20 min resuscitation.	No (score 3)	Incorrect aCTG-assessment; classified as suboptimal but later assessed as preterminal. This is not likely to be the cause of the SAE.		Cause stillbirth: Hb 1.5 mmol/l, major feto-maternal transfusion.	
3	Emergency cesarean section	Indication for aCTG: Reduced fetal movements. GA: 28 + 5. Conclusion of primary care midwife: Suboptimal aCTG. Care management: Referral to secondary care. Follow-up: Conclusion of secondary care: Suboptimal aCTG. Ultrasound: intrauterine growth restriction and brain sparing. ACTG reconnected and abnormal aCTG. An emergency cesarean section followed. AS 5/8/9. CPAP. Birthweight 840 g (<p3).	No (score 0)				
4	Emergency cesarean section	Indication for aCTG: Reduced fetal movements. GA: 38 + 2. Conclusion of primary care midwife: Suboptimal aCTG. Care management: Referral to secondary care. Follow-up: Conclusion secondary care: Suboptimal aCTG. Ultrasound: normal. ACTG reconnected and abnormal aCTG. A few hours after referral, an emergency cesarean section followed. AS 9/10. Birthweight 2363 g (<p3).	No (score 0)				
5	Emergency cesarean section	Indication for aCTG: Reduced fetal movements. GA: 41 + 5. Conclusion of primary care midwife: non-reassuring aCTG. Care management: Referral to secondary care. Follow-up: Conclusion of secondary care: normal aCTG. Ultrasound: oligohydramnios. Advice: induction of labour; parents declined. During the night spontaneous onset of labour and abnormal aCTG. An emergency C-section followed. AS 8/8/10. Birthweight 2885 g (<p3).	No (score 0)				
6	Stillbirth	Indication for aCTG: Reduced fetal movements. GA: 35 + 1. Conclusion of primary care midwife: reassuring aCTG. Care management: Next-day ultrasound (within 24 h). Follow-up: Next-day ultrasound and fetal death diagnosed. Birthweight 3125 g. Cause of fetal death unknown	No (score 0)				
7	Emergency cesarean section	Indication for aCTG: Reduced fetal movements. GA: 40 + 1. Conclusion of primary care midwife: reassuring aCTG. Care management: regular care. Follow-up: A few hours after aCTG, assessment by a member of the quality committee; conclusion non-reassuring aCTG and advice directly referral to secondary care. Conclusion of secondary care: sinusoidal aCTG pattern. Emergency cesarean section followed. AS 1/8/9. Birthweight 3088 g (p40). Severe anaemia.	No (score 0)				

aCTG=antenatal cardiotocography

CRediT authorship contribution statement

Conceptualisation: Elise M. Neppelenbroek, Corine J.M. Verhoeven, Olivier W.H. van der Heijden, Ank de Jonge. **Data curation:** Elise M. Neppelenbroek, Corine J.M. Verhoeven. **Formal analysis:** Elise M. Neppelenbroek. **Funding acquisition:** Corine J.M. Verhoeven. **Methodology:** Elise M. Neppelenbroek, Corine J.M. Verhoeven, Olivier W.H. van der Heijden, Marit S.G. van der Pijl, Carola J.M. Groenen, Wessel Ganzevoort, Bas S.W.A. Nij Bijvank, Ank de Jonge. **Project administration:** Elise M. Neppelenbroek. **Supervision:** Corine J.M. Verhoeven, Olivier W.H. van der Heijden, Ank de Jonge. **Validation:** Elise M. Neppelenbroek, Corine J.M. Verhoeven. **Writing – original draft:** Elise M. Neppelenbroek. **Writing – review & editing:** Elise M. Neppelenbroek, Corine J.M. Verhoeven, Olivier W.H. van der Heijden, Marit S.G. van der Pijl, Carola J.M. Groenen, Wessel Ganzevoort, Bas S.W.A. Nij Bijvank, Ank de Jonge.

Declaration of Competing Interest

The authors report no conflicts of interest.

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Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.wombi.2023.08.006.

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