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Takeshita, Mai ; Toyomoto, Rie ; Marui, Kanae ; Ito, Masami ; Eto, Hiromi ; Takehara, Kenji ; Matsui, Mitsuaki

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Title

Cardiotocography use for foetal assessment during labour in low and middle-income countries: a scoping review

Authors

Mai Takeshita [1]*, Rie Toyomoto [2]*, Kanae Marui [1], Masami Ito [2], Hiromi Eto [3], Kenji Takehara [4], Mitsuaki Matsui [5,6]

* The first two authors contributed equally to this work.

Affiliations

1 Department of Health Informatics, Graduate School of Medicine / School of Public Health, Kyoto University, Japan

2 Department of Health Promotion and Human Behaviour, Graduate School of Medicine / School of Public Health, Kyoto University, Japan

3 Department of Reproductive Health, Institute of Biomedical Sciences, Nagasaki University, Japan

4 Department of Health Policy, Research Institute, National Center for Child Health and Development, Japan

5 Department of Global Health, Nagasaki University School of Tropical Medicine and Global Health, Japan

6 Department of Public Heath, Kobe University Graduate School of Health Sciences, Japan

Corresponding author:

Mitsuaki Matsui

e-mail: mmatsui@port.kobe-u.ac.jp

phone: +81 76 792 2555

Abstract

Background

The use of cardiotocography (CTG) to improve neonatal outcomes is controversial. The medical settings, subjects, utilizations, and interpretation guidelines of CTG are unclear for low- and middle-income countries (LMICs).

Objectives

To assess and review CTG use for studies identified in LMICs and provide insights on the potential for effective use of CTG to improve maternal and neonatal outcomes.

Search strategy

The databases Medline, CINAHL, EMBASE, and Cochrane Central Register of Controlled Trials (CENTRAL) were searched for published and unpublished literature through September 2023.

Selection criteria

Publications were identified which were conducted in LMICs, based on the World Bank list of economies for 2019; targeting pregnant women in childbirth; and focusing on the utilization of CTG and neonatal outcomes.

Data collection and analysis

Publications were screened, and duplicates were removed. A scoping review was conducted using PRISMA-ScR guidelines.

Main results

The searches generated 1157 hits, of which 67 studies were included in the review. In the studies there was considerable variation and ambiguity regarding the study settings, target populations, utilizations, timing, frequency, and duration of CTG. While caesarean section rates were extensively investigated as an outcome of studies of CTG itself and the effect of additional techniques on CTG, other clinically significant outcomes, including neonatal

mortality, were not well reported.

Conclusions

Variations and ambiguities were found in the use of CTG in LMICs. Due to the limited amount of evidence, studies are needed to examine CTG availability in the context of LMICs. (242 words)

Keywords

Cardiotocography, CTG, electronic foetal monitoring, low- and middle-income countries, prognosis, guidelines, foetal heart rate, neonatal outcomes

Synopsis

Cardiotocography (CTG) use in low- and middle-income countries (LMICs) lacks consistency and clarity, with limited evidence on outcomes. (18 words)

Introduction

Childbirth is an arduous event for mother and child, and is associated with maternal and infant mortality and subsequent health risks. CTG is believed to be capable of detecting foetal abnormal signs, such as hypoxia and acidosis, especially in risk pregnancies [1]. Although the application of cardiotocography (CTG) during childbirth is widely used in developed countries, there is debate about its use in developing countries, especially in improving neonatal outcomes [2]. The latest WHO guidelines do not recommend routine CTG use on admission and continuous CTG during labour for healthy pregnant women [3]. The rationale for this guideline may include the fact that recent studies have shown that the routine use of CTG during delivery increases the caesarean section rate, without significantly reducing foetal or neonatal deaths. In a Cochrane review on the impacts of CTG use on maternal and neonatal outcomes, Alfirevic et al. showed that continuous CTG throughout labour reduces neonatal seizures but does not affect cerebral palsy, infant mortality, or other neonatal outcomes; and it increases caesarean sections and instrumental vaginal births [4]. In a second Cochrane review, Devane et al. indicated that admission CTG in labour did not benefit low-risk women [5]. The studies included in these reviews for which the evidence supported the recommendations, primarily came from high-income countries (HICs). The WHO guidelines based on these reviews state that the use of intermittent CTG in LMICs may increase detection of foetal heart rate abnormalities, which may lead to more caesarean sections being performed for perinatal hypoxia-ischemia and neonatal seizures. The evidence on how CTG should be used in low- and middle-income countries (LMICs) is lacking, and careful consideration should be given to whether LMICs should adopt the WHO recommendations based on evidence from many studies conducted in HICs.

In contrast, low- and middle-income countries (LMICs) face approximately 2.4 million newborn deaths and nearly 2 million stillbirths annually. In this context, there is an

urgent need for expeditious risk assessment and medical intervention [6]. Hence, it remains questionable whether the findings obtained in HICs can be applied to LMICs, which have different medical systems and levels. Furthermore, despite various CTG studies being conducted in LMICs, it is not clear what medical settings, subjects, monitoring methods, and interpretation methods are used by experts and guidelines for the use of CTG.

To explore the strategies for CTG use, we conducted a scoping review to summarize the CTG use of each study, including monitoring methods, evaluation methods, and impact in LMICs. Our objective was to provide insights on the judicious use of CTG to improve neonatal outcomes.

Methods

This scoping review was conducted following the Preferred Reporting Items for Systematic Reviews and the Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) statement and the Arksey and O'Malley framework [7, 8]. The protocol of this scoping review has been registered in the Open Science Framework (OSF) (doi:10.17605/OSF.IO/U4KXZ).

Inclusion and exclusion criteria

This study used a search strategy based on the Population, Concept, and Context (PCC) model from the Joanna Briggs Institute to identify relevant literature [9]. Studies were included if they were 1) conducted in LMICs, based on the World Bank list of economies 2019; 2) targeted pregnant women in childbirth; 3) full-text original articles with a focus on utilisation and/or evaluation, implementation process of CTG, and neonatal outcomes; and 4) written in English, French, Spanish, Portuguese, German, or Chinese. Qualitative studies, reviews, case reports, letters, and conference abstracts were excluded.

Identifying relevant studies

To identify potentially published and unpublished literatures, the following bibliographic databases were searched up to September 2023: Medline, CINAHL, EMBASE and Cochrane Central Register of Controlled Trials (CENTRAL). Two search specialists developed the search strategies for each database. For the search keywords such as 'cardiotocography' or 'electronic foetal monitoring' were combined with 'labour', 'delivery', 'childbirth', and 'Parturition'. The detailed search terms and strategies can be found in the Appendix (eTable 1).

Screening

All identified literatures were uploaded to Rayyan (Rayyan Systems Inc., MA, USA.). After the removal of all identified duplicates, two pairs of reviewers independently performed an initial screening of titles and abstracts, followed by a second screening of full-text articles. Disagreements on study selection and data extraction were resolved through discussion between the two reviewers or with a third reviewer.

Data collection

One researcher performed data extraction using a team-validated form, while another researcher checked the data for accuracy. The data extraction form consisted of the following items.

1） Study characteristics

Author, year of publication, country, study aims, study setting, study design, and description of comparisons.

2） Information on CTG operations

i. Monitoring methods: target populations and risks, monitoring timing, and intervals. For target risks, the author provided definitions were prioritized. If no inclusion/exclusion criteria were written to determine risk classification, it was

assumed to be unclear.

ii. Evaluation methods: guidelines, evaluation criteria, next monitoring timing, and intervention timing.

iii. Impact: key findings and implications.

Summarizing the results

The characteristics of the included studies in Table 1 were summarized, and then the studies were categorized according to study settings and CTG operations outlined in Table 2. For studies investigating the effects of CTG and additional techniques on neonatal outcomes, the odds ratio (OR) was recorded for each maternal and neonatal outcome in Table 3. If an individual study failed to report an OR, we imputed the OR from Mean ± SD assuming a normal distribution [10]. To account for computational issues that arose when an event was not observed in one group in an individual study, we added a fixed value of 0.5 according to the Cochrane Handbook [11]. The number of events used to calculate the ORs for each study is described in the Appendix (eTable 2).

Results

Search results

Figure 1 presents our study selection process. After removing 340 duplicate records, we identified 1177 records relevant to this review and screened all titles and abstracts. At this stage, we excluded 964 records that did not meet the study criteria for the Population, Concept, and Context (PCC) model from the Joanna Briggs Institute. We then performed a full-text review of 210 articles and excluded an additional 143. Finally, we included 67 studies in the study for extraction of data [12-79].

Included studies

Table 1 provides the characteristics of the included studies. Our review identified eight intervention studies, including randomized controlled trials (RCTs) [12, 13, 18-20, 23] and quasi-experimental studies[17, 22]; and fifty-nine observational studies, including cohort studies [15, 24-26, 28-30, 32, 34, 36-38, 40, 41, 43, 46, 47, 50, 56-58, 61, 63, 65-71, 73-75, 77, 78], case-control studies [27, 33, 35, 39, 42, 44, 45, 48, 49, 52, 53, 55, 62, 64, 72], before and after studies[14, 16, 21, 31], and cross-sectional studies [51, 54, 60, 76, 79]. These studies were published between 1974 and 2023. Of the sixty-seven studies included in the review, which were all conducted in lower-middle or upper-middle income countries, twenty-eight (54%) were in India [13, 15, 19, 23, 24, 29, 32, 34, 37, 41, 44, 46, 50, 57, 58, 61, 65, 67-69, 71-77, 79], followed by five (7%) each in China [28, 33, 53, 55, 66] and Pakistan [22, 35, 40, 54, 60], and four (6%) each in South Africa [21, 25-27] and Iran [18, 47, 49, 51].

According to the study objectives, the included studies were classified into three main categories: i) efficacy of CTG; ii) techniques to enhance the usefulness of CTG; and iii) evaluation criteria for CTG waveform, and relationship between CTG. To evaluate the efficacy of CTG, seven studies compared continuous or intermittent CTG groups with Doppler ultrasound or Pinard Intermittent Auscultation groups or no CTG [12-18]. These were published between 1994 and 2020, and the studies included three RCTs for signatures, a quasi-experimental study, a cohort study, and two before and after studies. Due to its limited diagnostic accuracy, five studies aimed at technology validation attempted to predict foetal hypoxemia by combining CTG with other monitoring techniques. These were published between 2013 and 2022, and the studies included three RCTs, a quasi-experimental study, and one before and after study. In this study, monitoring techniques included vibroacoustic stimulation [19], CTG with a computerized decision support system [20], foetal scalp blood sampling [22], education package of foetal heart rate monitoring [21], and foetal acoustic

stimulation [23]. The majority of the fifty-five studies aimed at validating CTG waveform assessment methods were published between 1974 and 2023, and the studies included thirty-four cohort studies, thirteen case control studies, six cross sectional study, a before and after study, and a nested case control study. These were focused on CTG waveform patterns and maternal and infant outcomes, while others focused on the agreement of CTG interpretation among physicians with varying years of experience [66] and compared 3- and 5-tiered guidelines combined with maternal and foetal risk factors such as other complications, pregnancy progression, and foetal growth [52], or combined with the Fetal Reserve Index to predict acidemia or asphyxia to predict acidemia or asphyxia [70]. In addition, considering the COVID-19 pandemic, one study compared CTG changes during parturition in the COVID-19 seropositive mothers and healthy controls [64].

CTG Operations

CTG operations in the included studies are shown in Table 2. All studies were conducted in lower- or upper-middle-income countries. Tertiary care facilities were the most common study setting, with fifty-five (82%). Subjects ranged from low to high risk, and CTG was used at admissions in nineteen (28%) studies, at admissions and deliveries in seventeen (25%) studies. Monitoring was intermittent in twenty-three studies (34%), continuous in fifteen studies (22%), and unclear in thirty studies (45%). As for how to interpret CTGs, NICHD/ACOG guidelines were used in fifteen studies (22%), FIGO guidelines in eight studies (12%), NICE guidelines in fifteen studies (22%), RCOG guidelines in four studies (6%), and unstated guidelines in eighteen studies (27%). eTable 3 presents detailed information on CTG operations.

Effects of CTG and additional monitoring techniques on CTG

Table 3 shows the results for each outcome from studies examining the efficacy of CTG and additional technologies. The eTable 2 provides the sample sizes and the number of events reported in each study. In studies on the efficacy of CTG, the caesarean section rates varied across studies, with some studies below 5% and others above 50%. Five of the seven studies found that CTG use was associated with an increase in caesarean sections compared to intermitted auscultation (IA) [12, 15-18].

The addition of other technologies to CTG tended to reduce the caesarean section rate more effectively than CTG alone [20-22]. Regarding other perinatal outcomes, eight studies reported on 5-minute Apgar scores [12, 13, 16, 18-21, 23], and nine studies on NICU admissions [12, 13, 16-21, 23]. Perinatal deaths were reported in half of the studies [12, 14-17, 19, 20]; and in two studies, no events were observed in either group. Two studies reported meconium aspiration syndrome [13, 17], hypoxic encephalopathy [13, 19], and acidemia [20, 23].

Discussion

This scoping review revealed considerable variations and uncertainties in CTG administration; encompassing factors across individual studies such as target population, method of use, timing, frequency, and duration. The studies extensively examined caesarean section rates, both as a consequence of CTG utilization and in conjunction with additional techniques. Diverse rates of caesarean section were observed, ranging across studies from below 5% to over 50%. Crucial clinical outcomes, such as intrapartum and neonatal death, and neonatal morbidity, remained underreported. These results provide valuable insights into the operational feasibility of CTG in LMICs.

CTG Operations

CTG operational status varied across studies with respect to participant risk, timing, and monitoring duration, which hindered result comparison and interpretation. Approximately half of the studies were unclear whether CTG was used intermittently or continuously, and one-third lacked the information on guidelines for interpretation of CTG waveforms. Other studies followed various guidelines from academic societies and organizations. Previous research has highlighted differences in judgment and agreement among health care providers depending on the guidelines [80]. For example, most 3-tier guidelines lack direction for responding to Category II/suspicious cases, in contrast to the straightforward Category I/normal and Category III/pathological cases, thereby introducing complexities in medical response [81, 82]. Consequently, it is crucial to comprehend the advantages and disadvantages of using any guideline, not just the 3-tier, and to establish clear rules for medical personnel. Specific methodologies for CTG usage should be thoroughly discussed to enhance its efficiency.

Importantly, the majority of the studies occurred in middle-income tertiary hospitals. In such settings where the prior probability of foetal abnormality is high, CTG can be helpful in identifying high-risk fetuses and optimizing resource allocation in settings with limited antenatal risk assessment [83]. By contrast, CTG might not be well-suited for resource-limited settings because its equipment is costly and needing consumables like ultrasound gel, thermal paper, and electricity [84].

Effects of CTG and additional techniques

The trend observed in this review indicates that CTG increased caesarean sections compared to IA, and it demonstrated no significant differences in other perinatal outcomes. These findings are consistent with findings from previous reviews [4, 5, 83]. However, it is important to note that the decision to perform caesarean sections is influenced by a multitude

of factors. These factors encompass not only the diagnostic accuracy and efficacy of CTG but also subsequent resuscitation techniques, the intricacies of the healthcare system, the perspectives and beliefs held by healthcare professionals, convenience considerations, and reimbursement policies [85]. Similar to earlier studies [86], the studies included in this review reveal a substantial disparity in caesarean section rates, ranging widely from less than 5% to over 50%. This variation highlights two distinct issues: unmet needs in cases of underutilization and the overuse of caesarean sections. Another point worth noting is that researchers tend to concentrate on measurable outcomes and not report clinically significant outcomes. For a comprehensive evaluation, it would be ideal to include low-incidence outcomes (i.e., maternal mortality and morbidity due to obstetric interventions, foetal/neonatal mortality, and neonatal severe morbidity), long-term outcomes (i.e., infant growth and developmental delays), maternal experience as a core outcome set for childbirth [5, 87, 88]. Moreover, when these outcomes were reported, the direction was inconsistent, and the 95% CI was wide. Therefore, it is difficult to accurately judge whether increased caesarean sections resolve unmet needs or cause additional unnecessary medical intervention.

The exploration of additional techniques, including computer aided cardiotocography (cCTG) and foetal scalp blood sampling for lactate or pH analysis, show promise in potentially reducing CS rates. A study by Al Wattar et al. demonstrated that scalp blood sampling reduced the caesarean section rate in pairwise comparisons [89], which is consistent with the results of this review. In contrast, the results were reversed in a network meta-analysis, with the authors attributing the reversal to quality and reporting variability among studies and small sample sizes. In recent years, additional techniques have been actively developed and investigated, and new evidence will be generated. Nonetheless, it is pertinent to acknowledge that certain techniques, for instance scalp blood sampling, while showing promise, exhibit a high degree of invasiveness and cost. This characteristic reduces the adaptability of LMICs

and makes it challenging to generalize clinical practice.

Strengths and limitations

A broad search of research on CTG in LMICs allowed us to organize the operationalization of CTG and identify evidence practice gaps. This will help identify problems and clarify areas for improvement.

We acknowledge several limitations of the proposed review. First, we cannot eliminate the possibility that an extensive search of other databases or consideration of more languages would have yielded different results. Second, only comparative studies were included. For example, papers describing the prognosis of abnormal cases were excluded. Third, we did not assess the quality of the included studies. Because the focus of this scoping study was not to quantify the effectiveness of CTG but to identify gaps in existing studies on CTG operations. Therefore, caution should be exercised in interpreting Table 3.

Clinical Implications

There was variability and ambiguity among studies in how CTG is used; thus, it is essential to establish specific clinical guidelines to ensure consistent and standardized care in the use of CTG.

Future research implications

When conducting a study, the operationalization of CTG should be defined, such as subjects, settings, timing, and guidelines. In addition, when evaluating the effects of CTG and additional monitoring techniques, sample sizes should be calculated appropriately and critical outcome assessments, such as foetal and/or neonatal mortality and morbidity, long-term health outcomes, maternal experience, and costs, should be conducted. Approximately 80% of the

studies identified in this review were conducted in higher tertiary care institutions in middle-income countries; and therefore, studies from different healthcare settings, especially low-income countries and primary and secondary healthcare facilities, are needed.

Conclusion

In this scoping review, we found that the studies on CTG were primarily conducted in specific settings within tertiary care institutions in middle-income countries. Moreover, we observed variations and ambiguity in the utilization of CTG. We further discovered that clinically important outcomes, including neonatal mortality, were either not reported or not detectable due to limited sample sizes.

Contributors

MT, RT, and MM designed the study in repeated consultations with EH, and KT. Data were extracted by MT, RT, KM, and MI. MT and RT drafted the first manuscript, while KM, MI, EH, TK, and MM made critical contributions to the manuscript. All the authors have seen the final manuscript and approved it for submission.

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Conflict of interest

All authors declare no conflicts of interests.

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Figure 1. PRISMA 2020 flow diagram.

Table 1. Characteristics of included studies.

Footnotes: Pregnancy risk determination was based on either: authors' specific mention of "low risk", "mixed risk", and "high risk" pregnancies OR based on maternal and fetal risk factors described in the text. If no information was available on maternal factors, then it was defined as unclear.
CTG: cardiotocography, EFM: electronic fetal monitoring, IA: intermittent auscultation

Table 2. CTG usage environment and operational status (N=58).

Footnotes: [a]There are duplications.

Table 3. Outcomes from studies examining the efficacy of CTG and techniques to enhance the usefulness of CTG.

Footnote: [a]CS and/or operative vaginal delivery, [b]Apgar score<6 and converted from Mean±SD, [c]all subjects in the CTG group had non-reactive CTG pattern and caesarean section, [d]adjust by adding or subtracting 0.5.

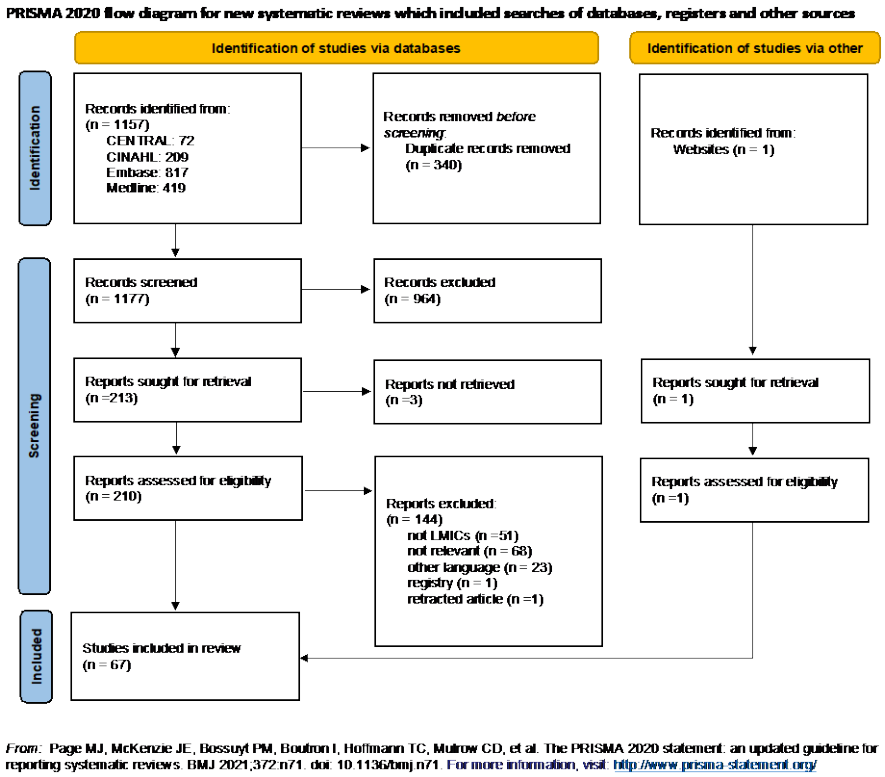
eTable 1. Embase search strategies.

eTable 2. The sample sizes and the number of events reported in each study.

Footnote: [a]Event_CS and/or operative vaginal delivery, [b]These events were excluded by the analysis due to exclusion criteria, [c]Apgar score<6, [d]Converted from Mean±SD, [e]all subjects in the CTG group had non-reactive CTG pattern and caesarean section, [f]different denominators.

eTable 3. The detailed information on CTG operations.

Figure 1. PRISMA 2020 flow diagram.



From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71. For more information, visit: http://www.prisma-statement.org/