ΠΑΝΕΠΙΣΤΗΜΙΟ ΔΥΤΙΚΗΣ ΑΤΤΙΚΗΣ

ΣΧΟΛΗ ΕΠΑΓΓΕΛΜΑΤΩΝ ΥΓΕΙΑΣ ΚΑΙ ΠΡΟΝΟΙΑΣ

ΤΜΗΜΑ ΜΑΙΕΥΤΙΚΗΣ

ΠΡΟΗΓΜΕΝΗ ΚΑΙ ΤΕΚΜΗΡΙΩΜΕΝΗ ΜΑΙΕΥΤΙΚΗ ΦΡΟΝΤΙΔΑ

Μεταπτυχιακή Διπλωματική Εργασία

Περιγεννητικά αποτελέσματα με την χρήση συμβατικής ανάλυσης του καρδιοτοκογραφήματος έναντι αυτοματοποιημένης ανάλυσης του

Φοιτητής:

Τσιπούρα Αικατερίνη

Α.Μ.: 20069

Επιβλέπουσα Καθηγήτρια:

Γουρουντή Κλεάνθη

Αναπληρώτρια Καθηγήτρια

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Conventional cardiotocography versus computerized CTG analysis and perinatal outcomes: a systematic review

Student:

Tsipoura Aikaterini

Registration Number: 20069

Supervisor:

Gourounti Kleanthi

Assistant Professor

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ΠΑΝΕΠΙΣΤΗΜΙΟ ΔΥΤΙΚΗΣ ΑΤΤΙΚΗΣ

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Περιγεννητικά αποτελέσματα με την χρήση συμβατικής ανάλυσης του καρδιοτοκογραφήματος έναντι αυτοματοποιημένης ανάλυσης του

Μέλη Εξεταστικής Επιτροπής συμπεριλαμβανομένου και του Εισηγητή

Α/α	ΟΝΟΜΑ ΕΠΩΝΥΜΟ	ΒΑΘΜΙΔΑ/ΙΔΙΟΤΗΤΑ	ΨΗΦΙΑΚΗ ΥΠΟΓΡΑΦΗ
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3	ΣΑΡΑΝΤΑΚΗ ΑΝΤΙΓΟΝΗ	ΑΝΑΠΛΗΡΩΤΡΙΑ ΚΑΘΗΓΗΤΡΙΑ ΠΑ.Δ.Α.	Antigoni Sarantaki Digitally signed by Antigoni Sarantaki Date: 2024.01.27 16:46:47 +02'00'

ΔΗΛΩΣΗ ΣΥΓΓΡΑΦΕΑ ΔΙΠΛΩΜΑΤΙΚΗΣ ΕΡΓΑΣΙΑΣ

Η κάτωθι υπογεγραμμένη Τσιπούρα Αικατερίνη του Γεωργίου, με αριθμό μητρώου 20069 φοιτήτρια του Προγράμματος Μεταπτυχιακών Σπουδών Προηγμένη και Τεκμηριωμένη Μαιευτική Φροντίδα του Τμήματος Μαιευτικής της Σχολής Επαγγελμάτων Υγείας και Πρόνοιας του Πανεπιστημίου Δυτικής Αττικής, δηλώνω ότι:

«Είμαι συγγραφέας αυτής της μεταπτυχιακής εργασίας και ότι κάθε βοήθεια την οποία είχα για την προετοιμασία της, είναι πλήρως αναγνωρισμένη και αναφέρεται στην εργασία. Επίσης, οι όποιες πηγές από τις οποίες έκανα χρήση δεδομένων, ιδεών ή λέξεων, είτε ακριβώς είτε παραφρασμένες, αναφέρονται στο σύνολό τους, με πλήρη αναφορά στους συγγραφείς, τον εκδοτικό οίκο ή το περιοδικό, συμπεριλαμβανομένων και των πηγών που ενδεχομένως χρησιμοποιήθηκαν από το διαδίκτυο. Επίσης, βεβαιώνω ότι αυτή η εργασία έχει συγγραφεί από μένα αποκλειστικά και αποτελεί προϊόν πνευματικής ιδιοκτησίας τόσο δικής μου, όσο και του Ιδρύματος.

Παράβαση της ανωτέρω ακαδημαϊκής μου ευθύνης αποτελεί ουσιώδη λόγο για την ανάκληση του πτυχίου μου».

*****_Επιθυμώ την απαγόρευση πρόσβασης στο πλήρες κείμενο της εργασίας μου μέχρι …… και έπειτα από αίτηση μου στη Βιβλιοθήκη και έγκριση του επιβλέποντα καθηγητή._

Η Δηλούσα

*** Τσιπούρα Αικατερίνη/ Φοιτήτρια Μεταπτυχιακών Σπουδών**

**** Εάν κάποιος επιθυμεί απαγόρευση πρόσβασης στην εργασία για χρονικό διάστημα 6-12 μηνών (embargo), θα πρέπει να υπογράψει ψηφιακά ο/η επιβλέπων/ουσα καθηγητής/τρια, για να γνωστοποιεί ότι είναι ενημερωμένος/η και συναινεί. Οι λόγοι χρονικού αποκλεισμού πρόσβασης περιγράφονται αναλυτικά στις πολιτικές του Ι.Α. (σελ. 6):***

https://www.uniwa.gr/wp-content/uploads/2021/01/%CE%A0%CE%BF%CE%BB%CE%B9%CF%84%CE%B9%CE%BA%CE%B5%CC%81%CF%82_%CE%99%CE%B4%CF%81%CF%85%CE%BC%CE%B1%CF%84%CE%B9%CE%BA%CE%BF%CF%85%CC%81_%CE%91%CF%80%CE%BF%CE%B8%CE%B5%CF%84%CE%B7%CF%81%CE%B9%CC%81%CE%BF%CF%85_final.pdf

Ευχαριστίες

Θα ήθελα να ευχαριστήσω την επιβλέπουσα καθηγήτρια κα Γουρουντή για την άψογη συνεργασία και την σωστή καθοδήγηση που μου παρείχε ώστε να γίνει μια σωστή και ολοκληρωμένη διπλωματική εργασία.

Δεν θα μπορούσα να παραβλέψω και να μην ευχαριστήσω τον σύζυγό μου που με υποστήριξε να συνεχίσω την εργασία μου.

Περιεχόμενα

Περίληψη

Εισαγωγή: Το καρδιοτοκογράφημα (ΚΤΓ) αποτελεί ένα βασικό και ευρέως χρησιμοποιούμενο εργαλείο για την αξιολόγηση του ‘’καλώς έχειν’’ του εμβρύου. Η κύρια δυσκολία στην ερμηνεία του ΚΤΓ είναι η υποκειμενικότητα των παρατηρητών. Η μεταβλητότητα μεταξύ τους είναι χαρακτηριστική για την ερμηνεία του ΚΤΓ. Μια πολλά υποσχόμενη απάντηση για τη μείωση αυτής της μεταβλητότητας μεταξύ των παρατηρητών είναι η αυτοματοποιημένη ανάλυση του Εμβρυϊκού Καρδιακού Ρυθμού (ΕΚΡ) με την χρήση λογισμικών προγραμμάτων. Επιπροσθέτως, η αυτοματοποιημένη ανάλυση συμβάλλει στη μείωση των δυσμενών περιγεννητικών αποτελεσμάτων σε μητέρα και έμβρυο. **Σκοπός:** Ο στόχος αυτής της συστηματικής ανασκόπησης ήταν η σύγκριση της συμβατικής και της αυτοματοποιημένης ανάλυσης του ΚΤΓ, για να διαπιστωθεί εάν η αυτοματοποιημένη ανάλυση του ΚΤΓ σχετίζεται με καλύτερα περιγεννητικά αποτελέσματα. **Μέθοδοι:** Από τον Μάιο έως τον Ιούνιο του 2023 πραγματοποιήθηκε αναζήτηση σε τρεις ηλεκτρονικές βάσεις δεδομένων που σχετίζονται με την ιατρική (PubMed, Scopus, Cochrane), προκειμένου να βρεθούν τυχαιοποιημένες ελεγχόμενες δοκιμές (RCT) στην αγγλική γλώσσα. Οι μελέτες αξιολογήθηκαν για την μεθοδολογική τους ποιότητα με την χρήση της λίστας ελέγχου CONSORT. Ο πληθυσμός-στόχος ήταν έγκυες γυναίκες ή γυναίκες σε τοκετό υπό καρδιοτοκογραφική παρακολούθηση. Η παρέμβαση ήταν η οπτική ανάλυση του ΚΤΓ και η παρέμβαση σύγκρισης ήταν η αυτοματοποιημένη ανάλυση του ΚΤΓ. Στις εκβάσεις συμπεριλαμβάνονται δυσμενή περιγεννητικά αποτελέσματα όπως ποσοστά καισαρικών τομών, επεμβατικών κολπικών τοκετών, εμβρυϊκής υποξίας, εισαγωγές σε νεογνική μονάδα και χαμηλής βαθμολογίας Apgar των νεογνών. **Αποτελέσματα:** Εξετάστηκαν συνολικά 47 μελέτες σχετικές με το θέμα, ωστόσο μόνο πέντε πληρούσαν όλα τα κριτήρια ένταξης. Τέσσερις από αυτές τις μελέτες έδειξαν ότι η αυτοματοποιημένη ανάλυση δεν φάνηκε να συμβάλλει σε σημαντική μείωση του ποσοστού μεταβολικής οξέωσης ή μαιευτικών παρεμβάσεων, εκτός από μια μελέτη που φάνηκε να έχει χαμηλότερο ποσοστό ανεπιθύμητων περιγεννητικών εκβάσεων σε σχέση με την συμβατική ΚΤΓ (με λήψη εμβρυϊκού αίματος). Ωστόσο, όλες οι ανασκοπήσεις προτείνουν περαιτέρω ανάπτυξη λογισμικών προγραμμάτων που θα βοηθούν τους ειδικούς στην λήψη σωστών αποφάσεων και περισσότερων μελετών (RCTs) μεγαλύτερης κλίμακας στο μέλλον. **Συμπεράσματα:** Η αυτοματοποιημένη ανάλυση του ΕΚΡ είναι μια πολλά υποσχόμενη λύση για τη μείωση των δυσμενών περιγεννητικών εκβάσεων και την εξάλειψη της μεταβλητότητας μεταξύ παρατηρητών.

Λέξεις-κλειδιά: CTG, εμβρυϊκή παρακολούθηση, ανάλυση υπολογιστή, αυτοματοποιημένη ανάλυση, περιγεννητικά αποτελέσματα.

Abstract

Introduction: Cardiotocography (CTG) constitute a major and generally used tool for assessment of the fetal well-being. The main difficulty in the interpretation of the CTG is the subjectivity. Inter and intra observer variability are substantival features of the interpretation of CTGs. An auspicious answer for reduction of inter and intra observer variability is the computerised analysis of Fetal Heart Rate (FHR). Moreover, computerised analysis contributes to the reduction of adverse maternal and fetal outcomes. **Objective:** The aim of this review was to compare visual and computerised analysis of CTG, for establishing whether computerized CTG is related with better perinatal outcomes. **Materials and Methods:** Three electronic medical related databases (PubMed, Scopus, Cochrane) were searched from May to June 2023 in order to find randomized control trials (RCTs) in English. Studies were evaluated for methodological quality with the CONSORT checklist. The target population was pregnant or intrapartum women into cardiotocographic monitoring. Intervention was the visual analysis of the CTG, and the comparison intervention was the computerized analysis of the CTG. Primary outcomes included adverse perinatal outcomes. **Results:** A total of 47 studies relevant with the topic were examined, however only five articles met all the inclusion and methodological criteria. Four of these studies demonstrated that computerized analysis had no significant reduction in the rate of metabolic acidosis or obstetric interventions, except one study found a lower incidence of adverse perinatal outcome compared to conventional CTG (with fetal blood sampling). However, all reviews propose further development of decision-support software and more large-scale RCT's in the future. **Conclusion:** The computerised analysis of FHR is a promising solution for the reduction of adverse perinatal outcomes and the elimination of the inter-observer and intra-observer variability.

Keywords: CTG, fetal monitoring, computer analysis, computerised analysis, perinatal outcomes.

ΓΕΝΙΚΟ ΜΕΡΟΣ

Background

Με την πάροδο των χρόνων, η αξιολόγηση του ΕΚΡ κατά τη διάρκεια της εγκυμοσύνης και του τοκετού αποτέλεσε πρωταρχικό ενδιαφέρον για τους μαιευτήρες και τις μαίες. Η πρώτη προσπάθεια ακρόασης του ΕΚΡ ήταν το 1895, όταν ένας Γάλλος μαιευτήρας, ο Adolphe Pinard, σχεδίασε το εμβρυοσκόπιο Pinard. Ύστερα από 40 έτη έρευνας της ιατρικής μηχανικής αναπτύχθηκε ο σύγχρονος καρδιοτοκογράφος. Στα τέλη της δεκαετίας του '60, το καρδιοτοκογράφημα (ΚΤΓ) εισήχθη για πρώτη φορά στη μαιευτική φροντίδα (1). Το ΚΤΓ, είναι ένα μη παρεμβατικό και εύκολο στην χρήση του εργαλείο, που μας παρέχει μια ταυτόχρονη παρουσίαση του ΕΚΡ και των συστολών της μήτρας (2). Μπορεί να υπάρχουν παραλλαγές ως προς την χρήση του ΚΤΓ, όπως διαλείπουσα ακρόαση εμβρυικών παλμών ή συνεχή καρδιοτοκογραφία, εσωτερική ή εξωτερική καρδιοτοκογραφία. Στην κλινική πράξη, η ευημερία του εμβρύου αναγνωρίζεται με την οπτική ανάλυση του ΚΤΓ. Η αξιολόγηση του είναι ζωτικής σημασίας, επειδή δεν αντικατοπτρίζει μόνο τη συμπεριφορά του καρδιαγγειακού συστήματος, αλλά μπορεί επίσης να παρέχει έμμεσες πληροφορίες για την κατάσταση του Αυτόνομου Νευρικού Συστήματος (ΑΝΣ), το οποίο ελέγχει τους κιρκάδιους ρυθμούς και ενδείξεις για τη νευρική ανάπτυξη του εμβρύου. Επιπλέον, κατά τη διάρκεια του τοκετού, μπορεί να βοηθήσει στον εντοπισμό της εμβρυικής υποξίας (2).

Το 1986, η Διεθνής Ομοσπονδία Γυναικολογίας και Μαιευτικής (FIGO) ανέπτυξε τα βασικά πρωτόκολλα για την αποσαφήνιση του ΚΤΓ, με βάση τις αλλαγές του ΕΚΡ συσχετιζόμενες με τις συστολές της μήτρας. Αυτά τα πρωτόκολλα περιλαμβάνουν παραμέτρους όπως η βασική γραμμή, η μεταβλητότητα, οι επιταχύνσεις, οι επιβραδύνσεις και το ημιτονοειδές μοτίβο (3). Για να αξιολογηθούν τα υπάρχοντα πρωτόκολλα ερμηνείας του ΕΚΡ, πραγματοποιήθηκαν σύγχρονες συστηματικές ανασκοπήσεις (4, 5). Παρόλο που υπάρχουν κλινικές κατευθυντήριες οδηγίες για την παροχή ενός πλαισίου αξιολόγησης και διαχείρισης των καταγραφών του ΚΤΓ εντός του τοκετού (6), η οπτική ανάλυση του υπόκειται σε διαφορές μεταξύ των παρατηρητών ως προς την εκτίμηση τους. Αυτή η διακύμανση μπορεί να αυξήσει τη συχνότητα των μη απαραίτητων επεμβατικών κολπικών τοκετών και των καισαρικών τομών (2, 7, 8). Μια προτεινόμενη λύση για την αντιμετώπιση του ζητήματος ήταν η ανάπτυξη ψηφιακών συστημάτων που βασίζονται σε υπολογιστές. Ως εκ τούτου, έχουν αναπτυχθεί πολλοί αλγόριθμοι για την ανάλυση του ΚΤΓ που παρέχουν αξιόπιστες και χρήσιμες οδηγίες ανάλυσης του και έχουν ως αποτέλεσμα την εξάλειψη αυτής της μεταβλητότητας μεταξύ ειδικών (2).

Στη δεκαετία του 1980, οι ερευνητές δημιούργησαν τα πρώτα προγράμματα με τη βοήθεια υπολογιστή που μπορούσαν να αναλύσουν αυτόματα τα σήματα του ΚΤΓ παρατηρώντας σημάδια εμβρυϊκής υποξίας κατά τον τοκετό. Αυτά τα συστήματα που χρησιμοποιούνται στην κλινική πρακτική σήμερα βασίζονται κυρίως στα πρωτόκολλα του FIGO. Οι Dawes και Redman ήταν οι πρώτοι που παρουσίασαν ένα πολλά υποσχόμενο μηχανογραφημένο σύστημα ανάλυσης τη δεκαετία του 1980. Στη συνέχεια, αναπτύχθηκαν άλλα ηλεκτρονικά συστήματα με σχετική μεθοδολογική βάση, όπως το σύστημα Omniview-SisPorto που αναπτύχθηκε από τους Ayres-de-Campos et al. το 1998 που περιλαμβάνει έναν ποσοτικό μετασχηματισμό των

συστάσεων της FIGO. Αυτό το σύστημα εξελίχθηκε με την πάροδο των χρόνων, με την πιο πρόσφατη έκδοση την SisPorto 4.0 το 2017. Την ίδια χρονολογία, οι Georgieva et al. δημοσίευσαν ένα νέο σύστημα (OxSys), το οποίο βασίζεται σε μία μόνο παράμετρο, τις επιβραδύνσεις και παρέχει ειδοποιήσεις σε πραγματικό χρόνο για τους επαγγελματίες υγείας (9).

ΕΙΔΙΚΟ ΜΕΡΟΣ

INTRODUCTION

Over the years, evaluation of the fetal heart rate (FHR) during pregnancy and labor has been of primary interest for obstetricians and midwives. The first attempt to hear the FHR was in 1895, when a French obstetrician, Adolphe Pinard, designed the Pinard horn-fetoscope. Since then, in late 60's, the cardiotocogram (CTG) was first introduced into maternity care (1). CTG, which is a non-operative and undemanding tool, provides us a coincident presentation of FHR and contractions of the uterus with the use of an ultrasound sensor located on the woman's abdomen (2). In clinical practice, the well-being of the fetus is recognized with visual analysis of the CTG. In 1986, International Federation of Gynecology and Obstetrics (FIGO) elaborated the primary general criteria for elucidation of CTG based on changes of FHR in relation to contraction. This interpretation includes parameters such as baseline, variability, accelerations, decelerations, and the sinusoidal pattern. Thereon, criteria have been altered and improved (3). Recent systematic reviews were conducted to compare existing CTG interpretation guidelines (4, 5). Even though there are clinical guidelines to provide a framework for evaluation and management of intrapartum fetal monitoring patterns (6), the visual analysis of FHR is subject to inter-observer and intra-observer variability. This variability can increase frequency of unnecessary operative vaginal births and cesarean deliveries (2, 7, 8). Therefore, many algorithms have been developed for the analysis of CTG and educe reliable and useful information to use as a guide to eliminate this variability through experts (2).

In 1980s, researchers created the first computer-assisted programs which could automatically analyze the signals of the CTG noticing signs of fetal hypoxia through labor. Those systems used in clinical practice nowadays are mainly based on FIGO's classification. FIGO's characteristics such as baseline, accelerations, decelerations, and variability were the groundwork for the construction of manageable rules to build proper signs of fetal hypoxia.

Dawes and Redman were the first to present a very promising computerized analysis system in the 1980s. The system is mostly based on features like the ones defined in FIGO's classification. Thereafter, other computerised systems with relevant methodologic basis were developed such as the Omniview-SisPorto system (Speculum S.A., Portugal) developed by Ayres-de-Campos et al. in 1998 that includes a numerical transformation of the FIGO's recommendations. This system developed over the years with the most recent version named SisPorto 4.0 in 2017. Recently, in 2017 Georgieva et al. published the OxSys system, which is primarily based on a single parameter, decelerations. Moreover, this system had real- time alerts for health professionals (9).

AIM

The aim of the present systematic review was to explore the available literature for comparing conventional analysis of CTG and computerised analysis of CTG in terms of better perinatal outcomes.

METHODS

Search strategy

A systematic review of electronic databases concerning medical care (PubMed-Medline, Scopus, and the Cochrane Library) was conducted from May to June 2023. The PubMed-Medline search terms were used according to PICO acronym as they are shown in Table 1. Search terms were customized to be suitable for each database.

In order to identify researches which had not raised from the primary search, we further investigated the reference lists of studies from the initial search. Two authors carried out the data collection and analysis at the same time.

Study selection

Inclusion criteria for eligible studies were the following:

- Target population: Pregnant or intrapartum women into cardiotocographic monitoring
- Intervention: Visual analysis of the CTG (conventional CTG)
- Comparison intervention: Computerised analysis of the CTG
- Outcomes: Perinatal outcomes (maternal and neonatal) such as cesarian section, operative vaginal delivery, fetal hypoxia, admissions to neonatal unit, and low Apgar score
- Study design: Randomized control trials (RCTs), English language

Quality assessment of included studies

Selected trials that met the inclusion criteria were evaluated for their reporting clarity by using the CONSORT statement. The CONSORT statement is a validated checklist consisting of 25 items (10). A presence of each item was recorded using Yes/No after reading the full text. We considered the CONSORT compliance rates as high compliance when they were higher than 85%, moderate compliance when they were between 70%-85% and low compliance when they were lower than 70%.

RESULTS

The initial search generated 47 studies. Titles and abstracts were examined for relevance to the aim of the present study. After screening, 2 studies were rejected as duplicates and 40 studies did not meet the inclusion criteria. Finally, only five studies were eligible for inclusion. This systematic review is comprised of the five remaining studies, data from these studies were analyzed and assessed for methodological quality. A flow diagram that illustrates the filtering process in the article is shown in Figure 1. The five studies that were eligible for inclusion, were also methodologically suitable. The characteristics and results of studies included are shown in Table 2.

The study by Ignatov and colleagues (11) is a RCT which conducted in Bulgaria in 2016 and aimed to evaluate the effectiveness of a computerized decision support system to reduce adverse perinatal outcomes compared to a conventional CTG. The sample of this study included 720 women in active labor, 360 women were randomized to the intervention group and 360 women were randomized to the control group. The intervention was a computerised decision support system that could calculate predicted pH values. In the control group, CTG traces were evaluated by clinicians according to

International Federation of Gynecology and Obstetrics (FIGO) guidelines and when an abnormal CTG trace presented it was performed a fetal blood sampling. After birth, blood gases were measured in all newborns in both study groups. Primary outcomes were hypoxia, acidemia, cesarean section, and use of forceps. Low Apgar score, newborn seizures, and admission to the neonatal intensive care unit (NICU) composed the secondary outcomes. The incidence of adverse perinatal outcomes was lower among women who were allocated to the intervention group compared to the women who were monitoring using the conventional with fetal blood sampling. More specifically, the above study support that there was a noteworthy reduction in fetal hypoxia, acidemia, cesarean section rate and admission to the NICU. The study by Ignatov et al. achieved moderate compliance to CONSORT checklist with almost 73% agreement.

The study by Nunes et al. (12) is a RCT which conducted in UK in 2017. The objective of the trial was to identify whether computerised analysis of the intrapartum CTG and real-time alerts can contribute to the reduction of obstetric intervention and/or neonatal metabolic acidosis when compared to conventional CTG. Nunes et al. studied 7.730 women in active labor (but not in active second stage) and 3.961 of them allocated to the computer CTG analysis and real-time alerts and the rest 3.769 allocated to visual analysis. Women randomized to the intervention arm had continuous CTG with computer analysis and real-time alerts in a central monitoring station. Women randomized to the control arm had continuous CTG, displayed in the same central monitoring station but without computer analysis or alerts. Primary outcome was incidence of newborn metabolic acidosis and secondary outcomes included operative delivery, low Apgar score, admission to neonatal intensive care unit, hypoxic–ischemic encephalopathy, and perinatal death. No significantly reduction of the rate of metabolic acidosis or obstetric intervention was found in the study arm. The authors proposed that continued refinement of interpretation algorithms may be required in the future. The study by Nunes et al. presented moderate compliance to CONSORT checklist with 81% agreement.

The study by Brocklehurst et al. (13) is a large RCT which conducted in UK and Ireland in 2017. The aim of the trial was to determine whether the help of a decision-support software in the analysis of CTG reflected the number of poor neonatal outcomes. Brocklehurst et al. studied 46.042 women (22.987 in the decision-support group and 23.055 in the no-decision-support group). Primary and secondary outcomes were separated to short term and long term. Adverse neonatal outcomes such as significant morbidity, death, and admission to neonatal care unit within 2 days after birth were the primary short term outcomes. Developmental progress at 2 years of age was related with long term outcomes. Secondary short-term outcomes related with neonatal (intrapartum stillbirth, low Apgar, seizures) and maternal (operative delivery, admission to higher level of care) and long-term outcomes related with infant such as vocabulary subscale, late deaths up to 2 years, major disability, and breastfeeding. No difference noted in the incidence of poor neonatal outcomes and to developmental assessment at the age of 2 years between the groups. The authors proposed that further development of decision-support software could improve assistance of the system provides to clinicians to change the outcomes. The study by Brocklehurst et al. showed high compliance to CONSORT checklist with almost 86% agreement.

The study by Saccone et al. (14) is a RCT conducted in Italy in 2021 that studied whether antenatal computerised analysis of CTG increase the rate of cesarean section in women with high-risk gestations. Saccone et al. researched 28 high-risk pregnancies. Women were divided into two groups (14 to control group and 14 were randomized to the intervention group). Women randomized to the computerised CTG arm had antenatal CTG with computerized analysis and real-time alerts in a central monitoring station. The CTG was connected to a system that analyzed parameters including baseline of FHR and short-term variability (STV). Women randomized to the control arm had antenatal CTG with standard non stress test (NST) with visual analysis and real-time alerts. Primary outcome was the incidence of cesarean delivery and secondary outcomes were preterm birth, gestational age at delivery, and neonatal outcomes such as birthweight, Apgar score, admission to the neonatal intensive care unit, and neonatal death. The result of the study was that the use of computerised CTG did not show a significant rise in cesarean delivery compared with standard CTG. As for secondary outcomes, there were no significant differences between groups in preterm birth, gestational age at delivery, Apgar score, and birth weight. No neonatal deaths were reported in the study population. The study by Saccone et al. achieved moderate compliance according to CONSORT checklist with almost 78% agreement.

Lastly, the study by Schroeder E. et al. in 2021 (15) is a cost-consequence analysis of individual patient data from the INFANT study, a large RCT-previously referred as the study by Brocklehurst et al. in 2017(13), which took place in maternity units in UK and Ireland. The objective was an economic evaluation of computerised analysis of CTG intrapartum. As in INFANT trial, 46.042 women and 46.614 infants were researched, and the intervention was the use of a computerised analysis support system. Statistics about unit costs were selected from national sources (Personal Social Services Research Unit, National Health Service-NHS Reference costs). The overall costs at 2 years after labor evaluated by combining charges from postpartum discharge to 1 year and 1-2 years after. Primary outcomes were number of poor neonatal outcomes or neonatal morbidity, developmental assessment at the age of 2 years, mean cost per mother and newborn from birth to hospital discharge and from then to 2 years follow up and assessment of maternal health related quality of life at 1 and 2 years follow up. No remarkable differences were found among intervention and control group in none of the primary outcomes; clinical or economical. The reviewers concluded that the use of computerised analysis intrapartum did not lead to additional maternal or neonatal benefit and to additional costs or savings to the NHS. The study by Schroeder E. et al. achieved moderate compliance according to CONSORT checklist with almost 84% agreement.

DISCUSSION

The purpose of this review is to compare visual and computerised analysis of CTG in terms of better perinatal outcomes, such as caesarian section, operative vaginal delivery, fetal hypoxia, admissions to neonatal unit, and low Apgar. Furthermore, variability through experts' and clinicians' interpretations was an additional reason to examine.

In recent decades, CTG has remained the main method for screening the well-being of the fetus. Since 1895 until today, a rapid progress has been made to analyze the CTG signals for fetal hypoxia. Many studies are related with the analysis of the CTG and the

way to analyze it and confirm the well-being of the fetus. The main difficulty in the interpretation of the CTG is the subjectivity. Inter and intra observer variability are substantival features of the interpretation of CTGs. Variation in the interpretation of visual analysis of CTG was reviewed by several researchers. By way of illustration, Devane and colloquies in 2005 (16), examined intra and inter observer agreement in midwives' visual interpretations of intrapartum CTGs. Additionally, Bernardes and colleagues in 1997 (17), evaluated interobserver agreement in visual analysis by three expert obstetricians, and Amadori and colleagues, in 2022 (18), evaluated intra and inter operator agreement both midwives and obstetricians in CTG and whether their educational background influenced the result. All the above studies demonstrated the need to develop non-invasive methods of CTG assessment in childbirth. In particular, Bernardes et al. and Amadori et al. proposed electronic analysis of CTG as a suitable solution to eliminate inter-observer and intra-observer variability.

Towards this direction, several studies reviewed the contribution of computerised analysis to CTG's optimal interpretation. The findings of this systematic review of relevant studies have shown that computerized CTG, has not significantly reduced the rate of metabolic acidosis or obstetric intervention. Only, one study by Ignatov et al. in 2016 (11) had shown a lower incidence of adverse perinatal outcomes with the computerised decision support system that could calculate predicted pH values.

However, it is worthwhile to mention a prospective review which conducted by Costa and colleagues in 2010 (19). The above study examined how the use of computerised analysis of CTG altered experts' prediction of umbilical artery blood (UAB) pH and Apgar score in first 5 minutes from birth. The total number of CTG tracings were randomised to the intervention arm, which had a computer analysis system support and to the control arm, which were without support of computer analysis system. All tracings were evaluated independently by three experts. Those experts had to predict the UAB pH of newborns and 5-minute Apgar. It was found that when clinicians had access to computerised analysis of the CTG tracings they had significantly higher agreement and accuracy in prediction of UAB pH. There were also seen in the intervention arm an increased interobserver agreement in prediction of 5-minute Apgar, but not too high to reach statistical significance. The authors identified that experts' previous experience with the system may made an impact to the results.

Although, the summation of this review proposes further development of decision-support software and more large-scale RCT's in the future. RCT's with larger amount of sample size should be conducted to have more statistically remarkable results.

The strength of this research is that it is a contemporary review, that was conducted between April until June 2023. The included studies are recent, with publication dates from 2016 to 2021. However, there are some limitations about this systematic review. There are only 5 studies eligible for inclusion to the review and the included studies have restrictions such as small sample size, long recruitment period and reproducibility among countries may be challenging.

CONCLUSION

In this systematic review, we established a recent and thorough search of the existing data that compare visual and computerised analysis of CTG for assessing which method is related to better perinatal outcomes. According to our results, we found no significant difference between interventions, in contrast to our initial hypothesis.

The computerized analysis of FHR is a promising solution for reduction of adverse perinatal outcomes and the elimination of variability through experts' opinions. The technology will help reduce disputes between experts and provide a more reliable solution. The combination of experts and computer systems seems to be the best option. Finally, further large-scale randomized control trials comparing cardiotocography with or without computerised analysis could be useful for the development of optimal strategies in daily clinical practice.

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Table 1. Search terms used in the study according to the PICO acronym

Population		Intervention		Comparison Intervention		Outcomes
pregnancy OR pregnant women OR Intrapartum women OR gestation OR expecting OR laboring women	AND	CTG OR cardiotocography OR FHR monitoring OR fetal heart rate OR cardiotocogr*	AND	computer analysis OR computerised analysis OR computerized analysis OR automatic analysis OR artificial intelligence	AND	newborn outcome OR neonatal outcome OR perinatal outcome OR cesarean section OR delivery OR outcome

Figure 1. Flow Diagram illustrating article filtering process

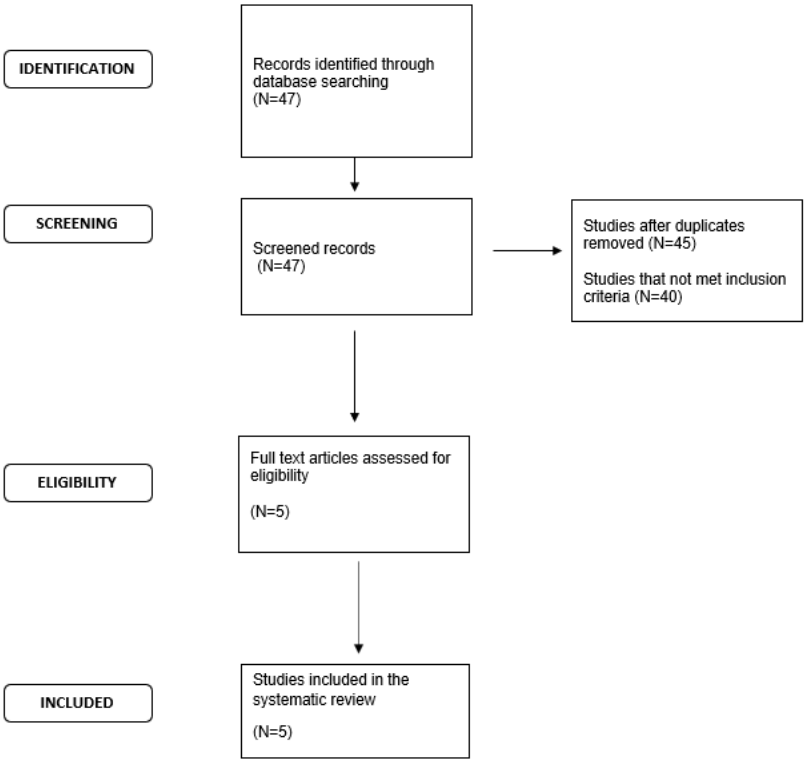

Table 2. Characteristics and results of studies included

	Ignatov P.N. et al., 2016	Nunes I. et al., 2017	Brocklehurst P. et al., 2018	Saccone G. et al., 2021	Schroeder E. et al., 2021
Study design	RCT	RCT	RCT	RCT	RCT (individual patient data from INFANT study)
Population	Intrapartum women in CTG	Intrapartum women in CTG	Intrapartum women in CTG	High risk pregnant women in CTG	Intrapartum women in CTG
Country	Bulgaria	UK	UK and Ireland	Italy	UK and Ireland
Sample size	720	7.730	46.042	28	46.042
Intervention	Visual analysis of CTG	Visual analysis of CTG	Visual analysis of CTG	Visual analysis of CTG	Visual analysis of CTG
Comparison	Computerised analysis of CTG	Computerised analysis of CTG	Computerised analysis of CTG	Computerised analysis of CTG	Computerised analysis of CTG
Outcomes	Reduction of adverse	Incidence of newborn metabolic	Number of poor neonatal outcomes or	Incidence of cesarean delivery,	Number of poor neonatal outcomes or

	perinatal outcomes	acidosis and adverse perinatal outcomes	neonatal morbidity and developmental assessment at the age of 2 years	preterm birth, gestation age at delivery and neonatal outcomes such as birthweight, Apgar score, admission to the neonatal intensive care unit, and neonatal death	neonatal morbidity, developmental assessment at the age of 2 years, mean cost per mother and infant from birth to hospital discharge and from then to 2 years follow up and assessment of maternal health related quality of life at 1 and 2 years follow up
Results	Lower incidence in fetal hypoxia and acidemia, lower risk of cesarean delivery, and decreased possibility for admission to neonatal intensive care unit when using computerised analysis of CTG	No significant reduction of metabolic acidosis or obstetric intervention between groups	No significant difference in incidence of poor neonatal outcomes and to developmental assessment at the age of 2 years between groups	No significant rise in incidence of cesarean delivery and no difference in preterm birth, gestational age at delivery, and neonatal outcomes such as birthweight, Apgar score, admission to the neonatal intensive care unit, and neonatal death	No significant differences among groups in none of primary outcomes (clinical or economical), no additional maternal or neonatal benefit and additional costs or savings to the NHS
CONSORT statement compliance	Moderate compliance (72,97%)	Moderate compliance (81,1%)	High compliance (86,49%)	Moderate compliance (78,38%)	Moderate compliance (83,78%)

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