Editorial

Recent Advances in Computerized Fetal Monitoring in Labor

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Abstract

More than two decades after the implementation of Computerized Cardiotocography (cCTG) in clinical practice, it is still hampered by controversies and lack of acceptance. This is mainly due to the fact that until now, there was no evidence that existing cCTG systems could reduce the likelihood of Cesarean delivery, forceps-assisted vaginal birth or adverse baby outcomes such as fetal hypoxia and/or acidaemia, brain injury due to lack of oxygen (neonatal seizures, hypoxic ischaemic encephalopathy), Apgar score less than seven at five minutes or admission to the Neonatal Intensive Care Unit (NICU). Recently however, it was demonstrated that monitoring of labor with a new cCTG system, called the "QSL Protocol", which is based on external computerized CTG, leads to a significant decrease in the occurrence of fetal hypoxia and operative deliveries, compared to standard CTG alone. Nevertheless, prior to the adoption of QSL Protocol as a gold standard in daily clinical practice, larger randomized control trials need to be conducted to assess its potential to detect rarer adverse events and stillbirth.

Introduction

Cardiotocography (CTG) is the current gold standard for fetal monitoring during labor. It is being used globally, on a daily basis. However, interpreting CTG traces can prove challenging, mainly due to significant differences in existing clinical practice guidelines. Extensive research has found that the same CTG trace may elicit inconsistent interpretations between maternity care providers (inter-and intra-observer variability), [1-8] which is disconcerting given the impact of CTG traces on clinical decision-making [9]. CTG has a relatively low specificity (a high false positive rate) for identifying fetal hypoxia and associated complications. As a result, cardiotocographic findings incorrectly identified as normal delay necessary interventions, potentially increasing the risk of hypoxia or metabolic acidosis in the infant, which often leads to occurrence of neonatal complications like seizures, encephalopathies, cerebral palsy, cognitive and neurological disorders or stillbirths [6]. Conversely, a trace incorrectly identified as abnormal may result in unnecessary intervention, such as induction of labor or Cesarean delivery. Given these clinical implications, in the last 30 years, substantial research has investigated the impact of CTG monitoring in its current form. It appears that using continuous standard CTG during labor leads to a significant decrease in the risk of neonatal seizures, although it doesn't decrease the risk of fetal hypoxia/acidosis and cerebral palsy. Interestingly, it was also associated with significantly higher rates of Cesarean sections and instrumental deliveries [9,10].

Can the Current State of Art be Improved?

It is currently assumed that existing observer variability in CTG interpretation can be minimized through the use of electronic algorithms, implemented in Expert Systems (ESs). Expert Systems (ESs) represent a type of applied artificial intelligence designed to assist in complex decision-making [11]. In a healthcare context, ESs synthesis a computerized knowledge base derived from expert opinion with individual patient data to guide users towards possible diagnosis or treatment decisions [11]. To process data, an ES may apply rule-based algorithms or neural networks (i.e. a model of pattern recognition based on previously collected data) [12]. Requirements for ESs vary; systems may be web-based or supported on a stand-alone personal computer. ESs are paperless and present data in real-time, which is critical in healthcare environments where changes in health status can occur rapidly. The potential for ESs in maternity care is well recognized, and as a result, there has been an increasing interest in developing ESs for CTG monitoring [9,13,14]. Whereas earlier versions displayed only limited successes, some advances have been made in intelligence software. Several observational studies have reported significantly improved levels of agreement between practitioners interpreting fetal heart rate patterns when assisted by an ES [13,15,16]. Nevertheless, until recently, there was no evidence that CTG with an ES reduces the likelihood of Cesarean delivery, forceps-assisted vaginal birth or adverse baby outcomes such as fetal hypoxia and/or acidaemia, brain injury due to lack of oxygen (neonatal seizures, hypoxic ischaemic encephalopathy), Apgar score less than seven at five minutes or admission to the Neonatal Intensive Care Unit (NICU). In late 2016, Ignatov et al. published the final results from a trial aiming to assess the effectiveness of a new ES called "QDS Protocol". It was demonstrated that monitoring of labor with the QSL Protocol, which is based on external computerized CTG, leads to a significant decrease in the occurrence of fetal hypoxia and operative deliveries, compared to standard CTG alone [17].

The QDS Protocol in Details

This ES is based on indirect quantitative cardiotocography (qCTG) [18]. It is currently integrated in the NEXUS/OBSTETRICS software package, formerly known as ARGUS (Nexus GMT, Frankfurt, Germany), which is one of several recognized fetal
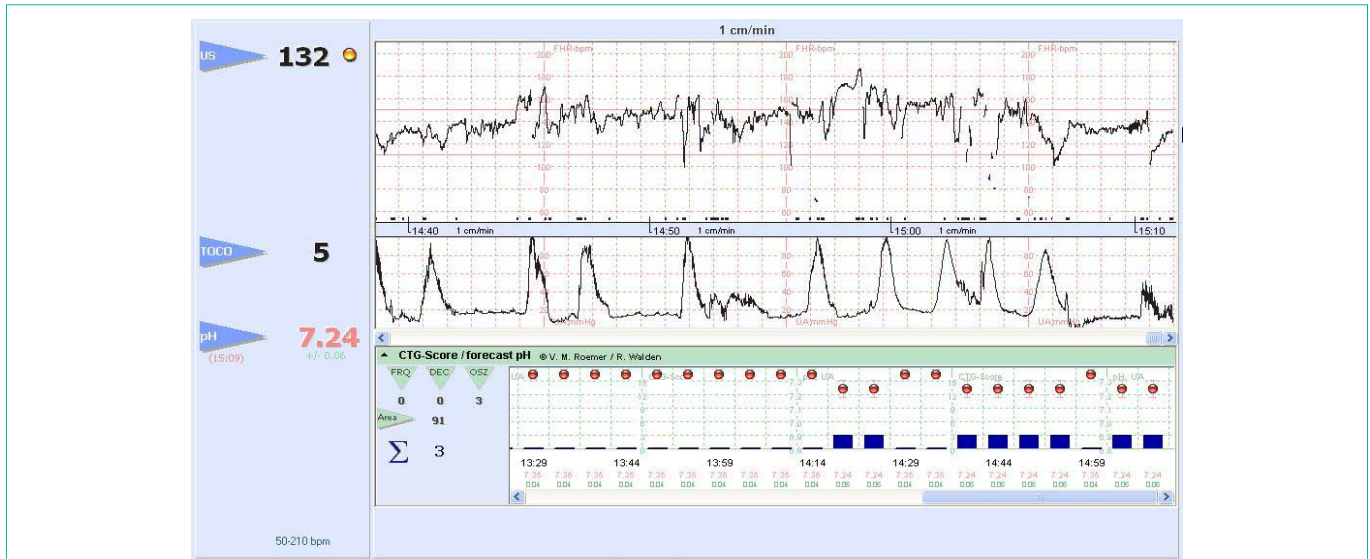
Figure 1: The NEXUS/OBSTETRICS computer interface with qCTG algorithm.

CTG finding	Prognostic pH values	CTG-score components	Management
Normal	7.350 – 7.237	all	**Expectant** intermittent monitoring
Suspect	7.237 – 7.137	OSZ / OSZ+FRQ / FRQ	**Expectant** continuous monitoring
		OSZ+DEC / DEC / FRQ+DEC / OSZ+FRQ+DEC	<30 mins **Continuous monitoring** >30 mins **Urgent delivery**
Abnormal	≤ 7.137	OSZ / OSZ+FRQ / FRQ	<30 mins **Continuous monitoring** >30 mins **Urgent delivery**
		OSZ+DEC / DEC / FRQ+DEC / OSZ+FRQ+DEC	**Urgent delivery**

Table 1: Guidelines for clinical application of the qCTG algorithm.
Abbreviations: CTG - cardiotocography; DEC –decelerations; FRQ - fetal heart rate; OSZ - microfluctuation

monitoring systems. The interface of NEXUS/OBSTETRICS with the qCTG module is shown on (Figure 1).

The CTG algorithm uses external monitoring to synthesize three CTG domains:

a)   Base Fetal Heart Rate (FRQ)

b)   Decelerations (DEC)

c)   Micro fluctuations in FHR (OSZ)

Notably, the domain "micro fluctuations" is distinct from fetal heart rate variability and refers to the number of extrema per minute, the mean beat-to-beat variability per minute and the oscillation amplitudes. Each of these three domains (a, b and c) is scored on a scale ranging between zero (normal measure) and six (highly abnormal measure) and summated for an overall CTG score. Thus, the overall CTG score ranges between zero (normal trace) and 18 (pre-terminal trace). As previously demonstrated, there is a strong correlation between the overall CTG score and fetal pH at delivery [18]. Based on these findings, the qCTG algorithm calculates predicted pH values which are updated every five minutes. As seen in (Figure 1), the most recently predicted pH value is displayed in red font on the left side of the interface; previous pH values are represented by red points in the white area below the CTG reading. Micro fluctuations in fetal heart rate, fetal heart rate and decelerations (abbreviated as OSZ, FRQ, and DEC respectively) are numerically presented on the lower left side of the interface. Using this original version of the NEXUS/OBSTETRICS system, equipped with qCTG algorithm, Ignatov and others [18,19] observed a substantial variability between predicted pH values and measurements of pH, taken from the umbilical artery of the newborn, immediately after delivery. This variability was in the range of -0.092 and +0.071, which prevented the system from being effective in clinical environment, rendering it unable to reduce the likelihood of Cesarean delivery, forceps-assisted vaginal birth or adverse baby outcomes such as fetal acidaemia, neonatal seizures, brain injury due to lack of oxygen
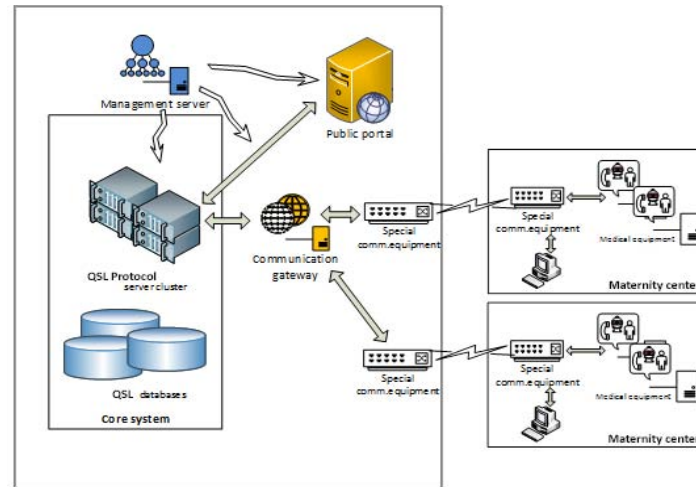
Figure 2: Block diagram of the QSL Protocol Expert system.

(hypoxic ischaemic encephalopathy), Apgar score less than seven at five minutes or admission to the NICU. Between 2007 and 2012, after additional validation work on the qCTG algorithm, Ignatov et al. were able to modify the NEXUS/OBSTETRICS system to enhance its prognostic ability:• It was demonstrated that when averaging the last six measurements taken prior to delivery, qCTG predicted pH values which ranged from -0.037 to +0.046 relative to the "true" pH value [19]. In a following study [20], Ignatov et al. observed that the major parameters of a CTG (micro fluctuations in fetal heart rate - OSZ, fetal heart rate - FRQ and decelerations - DEC) were not equal in terms of their prognostic ability of fetal pH, justifying the evaluation of specific subgroups of parameters. This proved to be a prerequisite for even more precise quantification of prognostic pH values and for generation of recommendations for specific obstetric management, based on the composition of the CTG-score. To account for the listed findings, guidelines for clinical application of the qCTG algorithm were developed [21] (Table 1) as shown above, the prognostic pH value classifies the findings into one of three groups (normal, suspect and abnormal), while the composition of the CTG-score defines the recommendation for obstetric management. Between 2012 and 2016, more studies [22,23] demonstrated that fetal monitoring with qCTG, used in accordance with the aforementioned clinical practice guidelines, leads to a statistically significant reduction in Cesarean deliveries and fetal hypoxia at birth. These findings led to the implementation of the clinical practice guidelines (Figure 2) in the qCTG algorithm's computer interface, thus defining the QSL (Quantitative Surveillance of Labor) Protocol. Apart from being the first ES to offer means for reducing Cesarean deliveries and fetal hypoxia at birth, the QSL Protocol has another important characteristic. It is installed on a centralized server cluster, allowing for remote connection with fetal monitors in labor wards, regardless of their geographic location.

Other Expert Systems

QSL Protocol, which is based on external computerized CTG (indirect fetal monitoring), has a very important advantage over standard indirect CTG. When an abnormal CTG trace is observed in current practice, invasive fetal blood sampling is often performed to assess fetal pH levels. This procedure includes making a small incision on the fetal head and taking a blood sample, which is then sent for analysis of pH and other parameters of the fetal acid-base balance [24]. Based mainly on the results for pH, clinicians can adopt the most appropriate obstetric management in order to avoid complications. However, the described invasive fetal blood sampling can only be performed at intermittent time points, in essence providing cross-sectional data. Time gaps between fetal blood samples may not capture the initial decline in fetal pH, consequently delaying timely diagnosis of hypoxia and appropriate obstetric interventions. Fetal blood sampling also requires a certain degree of cervical effacement, ruptured membranes, absence of vaginal infection, and trained staff to perform the procedure; these characteristics are not present in all deliveries. By providing continuous, non-invasive, real-time predicted pH values irrespective of cervical condition and membrane integrity, QSL Protocol circumvents these aforementioned issues. QSL Protocol has a critically important advantage over other ESs using internal CTG (direct fetal monitoring). A substantial amount of data [25-32] suggests that QSL Protocol identifies fetal oxygen deficiency very early - in the stage of hypoxemia and hypoxia, not asphyxia, e.g. before injury of vital organs such as fetal brain and heart could possibly occur, thus enabling healthcare providers to undertake timely measures in order to avoid complications and stillbirths. Internal CTG allows for recording of fetal electrocardiogram (ECG). ESs based on direct fetal monitoring are programmed to alert if ST-interval elevation in the ECG is detected. Elevation in the ST-interval is indicative for myocardial ischaemia (severe oxygen deficiency in the heart muscle, usually as a result of asphyxia), meaning that whenever alarm sounds, the fetus is already suffering from a pre-terminal condition. In that case, even if an immediate operative delivery is performed, the likelihood for occurrence of permanent heart/brain damage or even stillbirth is considerably high. On the other hand, QSL Protocol provides means for timely recognition of fetal oxygen deficiency which allows for a significant reduction in hypoxia/academia and Cesarean delivery, in relation to standard CTG and other ESs [17].

Discussion

In 2015, the Cochrane Collaboration published a large review on

"Expert systems for monitoring of labor" [9]. The aim was to evaluate the effectiveness of continuous or intermittent CTG monitoring during labor with an ES compared with continuous or intermittent CTG monitoring during labor without an ES or intermittent auscultation with a Pinard stethoscope or hand-held Doppler ultrasound device. Outcomes of interest included incidence of perinatal mortality, caesarean delivery, operative vaginal birth, fetal blood sampling, artificial rupture of amniotic membranes, oxytocin augmentation of labor, maternal satisfaction with labor, neonatal seizures, fetal acidemia, hypoxic ischaemic encephalopathy, admission to neonatal special care and/or neonatal intensive care unit and an Apgar score less than seven at five minutes [9]. Of the initial 206 published papers, only two preliminary trials met the inclusion criteria – one conducted in England (Brocklehurst 2013; 469 women - based on direct CTG, with ST-analysis of the fetal electrocardiogram) [14] and the other in Bulgaria (Ignatov 2012; 220 women – based on indirect CTG, using quantitative cardiotocography- qCTG) [22]. For the Brocklehurst 2013 trial, outcome assessors were aware of the intervention status for the analysis of the preliminary findings (confirmed through personal correspondence); thus there was a high risk of detection bias in this trial. In the Ignatov 2012 trial, outcome assessors were blinded to the intervention (confirmed through personal correspondence); therefore this trial was found to be at low risk for detection bias. In view of these biasing issues, only one trial was included in the quantitative analysis (Ignatov 2012). As it was already stated above, monitoring of labor with the QSL Protocol, based on external qCTG, leads to a significant decrease in the occurrence of fetal hypoxia and operative deliveries, compared to standard CTG alone [17]. On the other hand, the Brocklehurst's trial [33], which was also completed in early 2017, found no evidence that ESs based on internal CTG in conjunction with ST-analysis reduced the likelihood of hypoxia/academia and poor neonatal outcomes compared with standard cardiotocography alone. Furthermore, the biasing issues (which were identified earlier by Cochrane) culminated in a statement from one of the co-workers, who raised formal concerns regarding other study design weaknesses [34-42].

Conclusion

In a situation where clinical implementation of other expert systems for monitoring of labor does not result in a decrease of the incidence of operative deliveries and/or hypoxia in neonates, QSL Protocol seems to be the only solution for improving these outcome measures. Nevertheless, prior to the adoption of qCTG and QSL Protocol in daily clinical practice around the globe, a larger randomized control trial with greater sample size (including > 14 000 subjects) is underway to detect rarer adverse events like neonatal seizures, hypoxic-ischaemic encephalopathy, intracranial haemorrhage, cerebral palsy etc.), Apgar score less than seven at five minutes (Apgar < 7 at 5 min.) and stillbirths.

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