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FIGO GUIDELINES

FIGO consensus guidelines on intrapartum fetal monitoring: Adjunctive technologies^{☆★}

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1. Introduction

Cardiotocography (CTG) has a high sensitivity but only a limited specificity in predicting fetal hypoxia/acidosis [1]. In other words, a normal CTG is reassuring regarding the state of fetal oxygenation as hypoxia/acidosis is generally restricted to cases with suspicious or pathological patterns (see the definitions given in the CTG chapter [1]). However, a large number of fetuses with the latter patterns will not have clinically important hypoxia/acidosis [2,3]. To reduce such false positive cases and unnecessary medical interventions, adjunctive technologies have been proposed to further assess fetal oxygenation. These technologies should indicate intervention at an early stage of evolving fetal hypoxia/acidosis to prevent rather than to predict poor newborn outcome. Several adjunctive technologies have been developed over the last decades, including fetal blood sampling (FBS), continuous pH and lactate monitoring, fetal stimulation, pulse oximetry, and ST waveform analysis, and some of these have been successfully established.

Continuous fetal pH monitoring was developed in the 1970s; however, several technical difficulties arose, particularly surrounding the use of glass electrodes that could break in the fetal scalp, and the technique was subsequently abandoned. Fetal pulse oximetry was developed in the 1990s, but the commercialization of electrodes has subsequently been discontinued. A systematic review of four trials

comparing CTG + fetal pulse oximetry with isolated CTG showed no difference in the overall cesarean delivery rate (relative risk [RR] 0.99; 95% CI, 0.86–1.13), while adverse fetal outcomes were rare in both groups [4]. The present chapter focuses on the adjunctive technologies currently available for intrapartum fetal monitoring.

2. Fetal blood sampling for pH and lactate measurements

FBS during labor was first described in 1962 [5] and is currently used for assessment of fetal blood gases and/or lactate. Studies in fetal monkeys showed a good correlation of acid–base parameters between scalp and carotid blood [6], and human data have shown similar correlations between pH and lactate values obtained in scalp blood and those recorded shortly after birth in the umbilical artery and vein [7–11]. However, correlation of these values with newborn outcome depends on the time interval between scalp sampling and birth [12]. It has been argued that fetal capillary blood is likely to be affected by the redistribution of circulation occurring during fetal hypoxemia, and therefore it may not adequately represent the central circulation [13]. The opposite argument is that this aspect favors FBS because intrapartum fetal monitoring aims to identify fetuses in the early rather than in the late process of hypoxia.

2.1. Indications

FBS may be used in cases of suspicious or pathological CTG [1]. When pathological CTGs indicate a severe and acute event [1], immediate action should be taken and FBS is not advised as it would cause further delay.

2.2. Technique

To perform FBS a disposable or reusable FBS set can be used. It is necessary for the membranes to be ruptured and cervical dilation should be at least 3 cm. A vaginal examination needs to be performed prior to the procedure to assess the nature and position of the presenting part. The technique has similar contraindications to those of the fetal electrode: active genital herpes infection, women seropositive to hepatitis B, C, D, E, or to HIV, suspected fetal blood disorders, uncertainty about the presenting part, or when artificial rupture of membranes is inappropriate. An amnioscope (the diameter of which can vary according to cervical dilation) is inserted into the vagina and the lighting equipment is

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[★] The views expressed in this document reflect the opinion of the individuals and not necessarily those of the institutions that they represent.

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attached. With the amnioscope held tightly in place, the presenting part is dried using small swabs and a thin layer of paraffin is applied to the presenting part so that blood will form in a large drop and not spread over the skin, thus causing loss of carbon dioxide by diffusion. The incision on the fetal skin should not exceed 2 mm. After a blood drop has formed it is collected in a heparin-coated capillary. Following collection the incision site is inspected for persistent bleeding, which can usually be resolved with continuous pressure. In about 10% of attempts no pH information is obtained owing to blood clotting within the capillary, insufficient blood obtained, air bubbles inside the capillary, or a blood gas measurer that is calibrating at the time the sample needs to be analyzed. The failure rate when lactate analysis is performed is lower, at about 1.5% [14,15]. This is because for lactate analysis, approximately 5 μ L is needed as compared with 50 μ L that is required for blood gas assessment [15–17].

2.3. Interpretation of results

In three studies conducted in the 1960s, scalp pH values were evaluated in a total of 180 women with normal CTG tracings [18–20]. During the first stage of labor the lowest reported values were between 7.18 and 7.21. Based on these data, fetal acidosis during the first stage of labor was defined as a pH less than 7.20. This was later confirmed in a larger study including 306 fetuses [21].

In a large randomized controlled trial (RCT) comparing scalp pH and lactate measurements, the rate of operative deliveries was identical when cut-off values for intervention were set at pH less than 7.21 and lactate greater than 4.8 mmol/L; the latter value is commonly used to define the need for intervention [17]. However, cut-off values for lactate need to consider the apparatus used for measurement; the 4.8 mmol/L value was the only one to have been evaluated in this manner and was established with the Lactate Pro meter (Arkray, Kyoto, Japan). Further studies should also consider subgroup analysis to establish cut-off values by gestational age and stage of labor [14]. The interpretation of pH and lactate values is shown in Table 1 [22].

Intervention is indicated in cases of pH less than 7.20 or lactate greater than 4.8 mmol/L, and this should result in actions toward normalization of the CTG pattern or rapid delivery [1]. When the pH is between 7.20 and 7.25 or lactate is between 4.2 and 4.8 mmol/L [23], measures should be taken to improve fetal oxygenation. If the CTG abnormality persists or the pattern worsens, FBS should be repeated within 20–30 minutes. With a normal pH or lactate value no further action is usually required, but if the CTG remains grossly abnormal, FBS should be repeated within the next 60 minutes. A normal lactate measurement is strongly predictive of absent hypoxia/acidosis when performed in the last hour of labor [17,24]. With a continuously abnormal CTG pattern—even after three or more normal FBS results have been obtained—the fetus can still be safely delivered vaginally in about 60% of cases [25]. When three adequate FBS results have been obtained, consideration of further testing is rarely needed.

2.4. Does FBS improve fetal outcome?

There is uncertainty about whether the use of FBS as an adjunct to CTG—measuring either pH or lactate—improves neonatal outcome and reduces intervention rates. The first meta-analysis of RCTs comparing continuous CTG with intermittent auscultation for intrapartum fetal

monitoring, when analyzing the three trials in which FBS was not used as an adjunctive technology, found an almost three-fold increase in cesarean delivery rates in the CTG arm [26]. In the six trials in which FBS was used as an adjunct to CTG (CTG + FBS) the cesarean delivery rate was only 30% higher than in the intermittent auscultation arm, while neonatal seizures were reduced by 50%. In the only trial in which CTG with and without FBS were directly compared, cesarean delivery rates were 11% and 18%, respectively, but this difference was not statistically significant [27].

A 2013 Cochrane Review based on seven trials with FBS as an adjunctive technology and five with CTG only, found a relative risk of 1.34 for cesarean delivery in the former and 1.63 in the latter, when compared with intermittent auscultation [28]. Instrumental vaginal deliveries were somewhat higher in the CTG + FBS trials and acidosis in cord blood somewhat lower. A systematic review of the studies directly evaluating this technique concluded that, based on heterogeneous data of modest quality with somewhat inconsistent results, CTG + FBS “can provide additional information on fetal well-being” and “can reduce the risk of operative delivery” [29].

The National Institute of Clinical Excellence guidelines of 2014 consider that use of FBS “may help to reduce the need for further, more serious interventions” [22]. The guidelines of the Society of Obstetricians and Gynaecologists of Canada recommend FBS in association with CTG for uninterpretable or nonreassuring tracings, but consider the level of evidence to be moderate [30].

Altogether these data suggest that CTG + FBS results in a reduction in cesarean deliveries when compared with CTG alone. However, more than 50 years after its introduction, a high quality RCT is still needed to evaluate the effect of CTG with or without FBS on perinatal outcomes and intervention rates.

2.5. Limitations and risks

FBS use is mainly limited to central and northern Europe. The reason for the low global uptake of FBS may include that it is not particularly patient- or user-friendly. Moreover, it is time-consuming, with a median interval of 18 minutes between the decision to perform and the result [31]. This interval is significantly shorter when using point-of-care devices, with a median sampling interval of 2 minutes for lactate analysis using micro-volume meters [16]. A survey from Sweden published in 2014 concluded that FBS was well tolerated by laboring women, and clinicians did not consider it difficult to perform [32]. Given the dynamic nature of fetal hypoxia/acidosis during labor, the information provided by FBS quickly becomes outdated, requiring repetitions of the method. It is also difficult to perform in early labor and carries a small risk of infection and bleeding. Moreover, it requires laboratory support to evaluate blood gases and lactate, although bedside techniques have largely overcome this [33]. In the USA, FBS has been virtually abandoned following a paper suggesting that CTG, when properly interpreted, may be equal or superior in the prediction of both normal and adverse outcomes [34].

3. Fetal scalp stimulation

Fetal scalp stimulation (FSS) involves stimulating the fetal scalp by rubbing it with the examiner’s fingers or using forceps to clasp the fetal skin, or alternatively using vibroacoustic stimulation applied to the mother’s abdomen. Digital scalp stimulation is the most widely used as it is the easiest to perform, less invasive, and appears to have a similar predictive value for fetal hypoxia/acidosis to the other alternatives [35]. The main purpose of FSS is to evaluate fetuses showing reduced variability on CTG to distinguish between deep sleep and hypoxia/acidosis. It is of questionable value in other patterns. Observational studies have shown that when FSS leads to the appearance of an acceleration and subsequent normalization of the fetal heart pattern, this should be regarded as a reassuring feature, with a negative

Table 1
Interpretation of fetal blood sampling results regarding pH and lactate values.

pH	Lactate (mmol/L)	Interpretation
>7.25	<4.2	Normal
7.20–7.25	4.2–4.8	Intermediate
<7.20	>4.8	Abnormal

predictive value that is similar to pH greater than 7.25 on FBS [5,22]. When FSS does not elicit the appearance of accelerations, or when accelerations occur but continued reduced variability ensues [35], the positive predictive value for fetal hypoxia/acidosis is limited. In these situations continued monitoring and additional tests are necessary. It has been reported that in settings where FBS is used, FSS may reduce its need by about 50% [36].

4. Combined cardiocardiographic–electrocardiographic monitoring

Combined cardiocardiographic–electrocardiographic (CTG + ST) monitoring was commercialized in 2000 and associates continuous internal CTG monitoring with analysis of the fetal electrocardiogram ST segment morphology. The monitor evaluates 30 heart cycles to construct an average electrocardiographic signal that is then used for morphologic analysis of the ST segment (STAN; Neoventa, Gothenburg, Sweden). Information is obtained on the amplitude of the T-wave in relation to the QRS complex (T/QRS ratio) and on the shape of ST segments, which when showing an important part below the baseline are named grade 2 and 3 biphasic STs. Extensive animal experiments performed in the 1970s showed that during hypoxia, ST segment changes precede the signs of failing cardiovascular function [37,38]. The monitor provides automatic warnings called “ST events” when relevant changes are detected in ST segment analysis. The theoretical advantages of CTG + ST monitoring over FBS are its less invasive nature, an easier applicability during early labor, and the display of continuous information.

4.1. Indications

CTG + ST monitoring may be used to provide additional information about cardiac oxygenation in cases of suspicious or pathological CTG tracings [1]. When reduced variability and absent accelerations are already present on CTG, ST information cannot be reliably used to indicate fetal hypoxia/acidosis (see below). With pathological CTG indicating a severe and acute event [1], immediate action should be undertaken with or without the occurrence of ST events.

4.2. Technique

A fetal electrode is necessary to acquire continuous CTG + ST signals. Therefore, the technique has similar contraindications to internal CTG monitoring [1] and to FBS (see section above on the contraindications to FBS). The ST technology has not been extensively evaluated for gestational ages below 36 weeks.

4.3. Interpretation of results

Tracing interpretation needs to take into account the CTG pattern and the degree of ST changes. Specific guidelines were developed for CTG interpretation, inspired by the original FIGO guidelines of 1987, together with specific CTG + ST criteria for taking clinical action [39]. The system’s automatic warnings of ST events only occur when it detects changes in ECG morphology when compared with a previously existing state, and these changes may not be detectable if ECG morphology is already abnormal at the start of recording. Therefore, a “reactive CTG” (i.e. one showing normal variability and accelerations) or a normal FBS need to be documented at the start of monitoring for safe use of ST information. If FBS is not available, conservative measures to improve the CTG pattern can be considered (turning the laboring woman on her side, stopping oxytocin, acute tocolysis, reverting maternal hypotension if this was documented) before starting CTG + ST monitoring.

When the CTG is normal, ST events should be ignored as in this setting they do not indicate fetal hypoxia/acidosis. A few cases have been described in which CTG tracings have gradually changed from normal to pathological, without the appearance of ST events [40]. For this reason, any abnormal CTG lasting more than 60 minutes, or less if the

CTG pattern deteriorates rapidly, requires assessment by a senior obstetrician whether or not ST events occur. With a CTG showing persistently reduced variability or a pattern indicating a severe and acute hypoxic event, intervention is always required irrespective of ST data [39].

4.4. Does CTG + ST monitoring improve fetal outcome?

Six RCTs were published that compared CTG + ST monitoring with isolated CTG, for a total of more than 26 000 enrolled women [41–48]. The first trial used an earlier version of the technology, the first five trials were conducted in Europe using FBS as an adjunctive technique, and the most recent trial was performed in the USA, where a simplified three-tier CTG classification was used and FBS was not available. Several meta-analyses of the first five RCTs have been performed, but doubts remain as to whether the first trial should be included owing to the different version of the technology [49–53], and whether a more recent study [53] should be included because its entry criteria contradict the established CTG + ST guidelines.

All five European RCTs point to a reduction of FBS use of about 40% in the CTG + ST arm. Newborn metabolic acidosis was significantly lower in the CTG + ST arm in one of the larger trials, a similar trend was observed in two other large studies, and an opposite trend was seen in the two smaller trials. Operative deliveries (instrumental vaginal deliveries and cesarean deliveries) were significantly lower in the CTG + ST arm in one large study, showed a similar trend in another large study, and showed no difference in the remaining three studies. The 26-center USA trial enrolling 11 108 participants showed no differences in operative delivery or adverse neonatal outcome between the two arms [48].

A few centers have published data on neonatal outcome in the years following the introduction of the CTG + ST technology together with structured CTG training, and have reported progressive declines in the incidence of metabolic acidosis, with stable or decreasing intervention rates [54–56]. A causal relationship with the CTG + ST technology or with structured CTG training has not been established, but these unique outcomes deserve close attention. The importance of training and of prioritizing of the labor ward may have been underestimated. The ST technique is still relatively new and its guidelines were developed empirically. Further research is needed to evaluate whether changing management guidelines will improve the performance of the technique. Recently it has been suggested that biphasic STs do not add to the diagnostic value of the technique [57].

4.5. Limitations and risks

Clinical use of CTG + ST requires a relatively complex educational process. A CTG with normal variability and accelerations or a normal FBS is required at the start of monitoring for a confident evaluation of ST data, but even then hypoxia/acidosis can rarely develop during labor without the occurrence of ST events. Finally, ST events have been reported in about 50% of normally oxygenated fetuses, but only in 16% were they associated with abnormal CTG patterns warranting intervention according to the STAN guidelines [58].

5. Computer analysis of fetal monitoring signals

Computer analysis of CTGs was developed to overcome the poor interobserver agreement on tracing interpretation and to provide an objective evaluation of some CTG features that are difficult to assess visually, such as variability [1]. Over the last two decades, a small number of systems for computer analysis of intrapartum fetal monitoring signals have been commercialized, all in association with fetal central monitoring stations [59]: IntelliSpace Perinatal, incorporating the former OB TraceVue (Philips Healthcare, Eindhoven, Netherlands); Omniview-SisPorto (Speculum, Lisbon, Portugal) [60]; PeriCALM (PeriGen, Cranbury, NJ, USA) [61]; INFANT (K2 Medical Systems,

Plymouth, UK) [62]; and Trium CTG Online (GE Healthcare, Little Chalfont, UK and Trium Analysis Online GmbH, Munich, Germany).

These systems incorporate real-time visual and sound alerts for healthcare professionals based on the results of computer analysis of CTG or combined CTG + ST signals [60]. These alerts aim to raise attention to specific findings and prompt tracing re-evaluation, with subsequent action if considered necessary. All systems use relatively similar color-coding for alerts and refrain from providing clinical management recommendations. However, different mathematical algorithms are used and computer analysis is based on different interpretation guidelines.

Published research evaluating these systems is still relatively scarce. Computer analysis has been compared with that of experts and has generally yielded satisfactory results [63–67]. Comparisons between the systems are difficult as different numbers of observers and different observer experiences were selected. A small number of studies have evaluated the capacity of computer alerts to predict adverse neonatal outcomes [68–70]. The results suggest that it is possible to achieve a good prediction of newborn acidemia with computer analysis of CTG tracings acquired shortly before birth. Again, comparisons between studies are hampered by different case selection criteria and different choices of adverse neonatal outcome. Studies with larger sample sizes and direct comparisons of the different systems are lacking. Two of these systems have recently completed multicenter RCTs comparing them with standard CTG analysis [71,72], and their results are expected soon.

Computer analysis of intrapartum fetal monitoring signals is a relatively new but promising technology since optimization of the analysis algorithms will most likely continue. Currently, this technology should be used with caution as further research is necessary to evaluate its capacity to detect fetal hypoxia/acidosis and to prevent adverse outcomes.

6. Conclusion

There is still much uncertainty regarding the use of the different adjunctive technologies in intrapartum fetal monitoring. FSS is easy to perform and can be useful when reduced variability is the main CTG feature, as the appearance of accelerations and a change to a normal pattern is very predictive of absent hypoxia/acidosis. However, the benefits of this technique have not been evaluated in randomized trials and therefore little is known about how it affects neonatal outcome or intervention rates. FBS may reduce the incidence of operative deliveries, although the level of evidence for this is moderate and there is no evidence that fetal outcomes are improved. CTG + ST monitoring results in a lower need for FBS and perhaps in a modest reduction in operative deliveries. There is conflicting evidence as to whether it improves perinatal outcome. Computer analysis provides a reproducible and quantifiable approach to CTG and CTG + ST interpretation. It is a promising method to evaluate how different features/patterns relate to fetal outcome and perhaps to prompt healthcare professionals to act upon certain findings. Further studies are needed to compare the different computer systems and to evaluate how this technology affects intervention and adverse outcome rates.

Some experts consider that a better understanding of the pathophysiology of the fetal response to reduced oxygenation during labor is the main requisite for intrapartum fetal monitoring and, when repetitive decelerations occur, the presence of a stable baseline and normal variability obviates the need for adjunctive technologies and reduces the false positive rate of CTGs. However, adjunctive technologies will still need to be considered in the remaining cases.

Further research and development is needed in this field to remove the uncertainty that surrounds many of these adjunctive technologies and to provide more robust evidence on how they affect intervention and adverse outcome rates.

Conflict of interest

Diogo Ayres-de-Campos and João Bernardes are co-developers of the Omniview-SisPorto system. They do not receive funding from commercialization of the program, but the University of Porto receives royalties that are totally re-invested in research. Lawrence Devoe is a consultant for Neoventa Medical (Molndal, Sweden). Joscha Reinhard has received funding from Monica Healthcare Ltd (Nottingham, UK) for research conducted on noninvasive electrocardiographic monitoring. Austin Ugwumadu has received honorarium from Neoventa for delivering lectures on fetal monitoring.

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