

# FIGO CONSENSUS GUIDELINES ON INTRAPARTUM FETAL MONITORING

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Safe Motherhood and Newborn Health Committee

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## ADJUNCTIVE TECHNOLOGIES

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*The views expressed in this document reflect the opinion of the individuals and not necessarily of the institutions that they represent.*

## INTRODUCTION

As referred to in the previous chapter, cardiotocography (CTG) has a high sensitivity but only a limited specificity in predicting fetal hypoxia/acidosis. 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 definitions in previous chapter), however, a large number of fetuses with the latter patterns will not have clinically important hypoxia/acidosis<sup>1,2</sup>. 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 in order 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 (FS), pulse oximetry, and ST waveform analysis, and some of these have been successfully established.

Continuous fetal pH monitoring was developed in the 1970's, but several technical difficulties arose, particularly because glass electrodes could break in the fetal scalp, and the technique was

subsequently abandoned. Fetal pulse oximetry was developed in the 1990's, but the commercialisation of electrodes has subsequently been discontinued. A systematic review of four trials comparing CTG + fetal pulse oximetry with isolated CTG showed no difference in overall caesarean section rate (RR 0.99, 95% confidence intervals (CI) 0.86 to 1.13), while adverse fetal outcomes were rare in both groups <sup>3</sup>. This chapter will focus on currently available adjunctive technologies for intrapartum fetal monitoring.

### **FETAL BLOOD SAMPLING (FBS) FOR PH AND LACTATE MEASUREMENTS**

Fetal blood sampling (FBS) during labour was first introduced in 1962 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 <sup>5</sup>, 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 <sup>6-10</sup>. However, correlation of these values with newborn outcome depends on the time interval between scalp sampling and birth <sup>11</sup>. It has been argued that fetal capillary blood is likely to be affected by the redistribution of circulation occurring during fetal hypoxemia, and it therefore may not adequately represent the central circulation <sup>12</sup>. There is however the opposite argument that this aspect favours FBS, because intrapartum fetal monitoring aims to identify fetuses in the early rather than in the late process of hypoxia.

#### **Indications**

FBS may be used in cases of suspicious or pathological CTG tracings (see Chapter 3). When pathological CTGs indicate a severe and acute event (see Chapter 3), immediate action should be taken, and FBS is not advised, as it would cause further delay.

#### **Technique**

To perform FBS a disposable or re-usable 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 contra-indications to those of the fetal electrode: active genital herpes infection, women seropositive to hepatitis B, C, D, E, or to human immunodeficiency virus, 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 in the vagina, and the lighting equipment 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, in order for blood to form a large drop and to prevent it from spreading over the skin, thus causing loss of CO<sub>2</sub> by diffusion. The incision on the fetal skin should not exceed 2 mm and after a blood drop is formed, it is collected in a heparin-coated capillary. When this is concluded, 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, because of 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 analysed. The failure rate when lactate analysis is performed is lower, at about 1.5% <sup>13,14</sup>. This is due to the need of approximately 5 microlitres for the latter, instead of the 50 microlitres required for blood gas assessment <sup>14-16</sup>.

### 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 <sup>17-19</sup>. During the first stage of labour the lowest reported values were between 7.18 and 7.21. Based on these data, fetal acidosis during the first stage of labour was defined as a pH<7.20. This was later confirmed in a larger study including 306 fetuses <sup>20</sup>.

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<7.21 and lactate>4.8 mmol/l, and the latter value is commonly used to define the need for intervention <sup>16</sup>. However, cut-off values for lactate need to consider the apparatus used for measurement, and this value was the only one to have been evaluated in this manner, being established with the Lactate Pro™ meter (Arkray, Kyoto, Japan). Further studies should also consider sub-group analysis to establish cut-off values by gestational age and stage of labour <sup>13</sup>. The interpretation of pH and lactate values is shown in Table 1.

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

**Table 1.** Interpretation of FBS results regarding pH and lactate values (adapted from <sup>21</sup>)

Intervention is indicated in cases of pH<7.20 or lactate>4.8 mmol/l, and this should result in actions towards normalization of the CTG pattern or rapid delivery (see Chapter 3). When the pH is between 7.20 and 7.25, or lactate between 4.2 and 4.8 mmol/l <sup>22</sup>, measures should be taken to improve fetal oxygenation, and 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 labour <sup>16,23</sup>. With a continuously abnormal CTG pattern, even after three or more normal FBSs have been obtained, the fetus can still be safely delivered vaginally in about 60% of cases <sup>24</sup>. When three adequate FBS results have been obtained, consideration of further testing is rarely needed.

### **Does FBS improve fetal outcome?**

There is uncertainty on 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 analysing the three trials in which FBS was not used as an adjunctive technology, found an almost threefold increase in cesarean section rates in the CTG arm <sup>25</sup>. In the six trials in which FBS was used as an adjunct to CTG (CTG+FBS) the cesarean section 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 section rates were 11 and 18%, respectively, but this difference was not statistically significant <sup>26</sup>. A recent Cochrane review based on seven trials with FBS as an adjunctive technology and five with CTG only, found a RR of 1.34 for cesarean section in the former and of 1.63 in the latter as compared to intermittent auscultation <sup>27</sup>. Vaginal instrumental 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 wellbeing” and “can reduce the risk of operative delivery” <sup>28</sup>. 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” <sup>21</sup>. The guidelines of the Society of Obstetricians and Gynaecologists of Canada recommend FBS in association with CTG for uninterpretable or non-reassuring tracings, but consider the level of evidence to be moderate <sup>29</sup>. Altogether these data suggest that CTG+FBS results in a reduction in cesarean sections when compared to 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.

### **Limitations and risks**

FBS use is mainly limited to Central and Northern Europe. The reason for the low global uptake of FBS may include the fact that it is not very patient- or user-friendly. Moreover, it is time-consuming with a median interval of 18 minutes between the decision to perform and the result <sup>30</sup>. This interval is significantly shorter when using point-of-care devices, with a median sampling interval of two minutes for lactate analysis using micro-volume meters <sup>15</sup>. A recent survey from Sweden

concluded that FBS was well tolerated by laboring women, and clinicians did not consider it difficult to perform <sup>31</sup>. Given the dynamic nature of fetal hypoxia/acidosis during labour, the information provided by FBS quickly becomes outdated, requiring repetitions of the method. It is also difficult to perform in early labour 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 <sup>32</sup>. In the USA, FBS has virtually been abandoned following a paper suggesting that CTG, when properly interpreted, may be equal or superior in the prediction of both normal and adverse outcomes <sup>33</sup>.

### **FETAL SCALP STIMULATION (FSS)**

This technique involves the stimulation of the fetal scalp, by rubbing it with the examiner's fingers or using a forceps to clasp the fetal skin, or alternatively vibro-acoustic stimulation applied to the maternal 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 <sup>34</sup>. The main purpose of FSS is to evaluate fetuses showing reduced variability on the CTG, in order 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 normalisation of the fetal heart pattern, this should be regarded as a reassuring feature, with a negative predictive value that is similar to pH > 7.25 on FBS <sup>5,21</sup>. When FSS does not elicit the appearance of accelerations, or when accelerations occur but continued reduced variability ensues <sup>34</sup>, 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% <sup>35</sup>.

### **COMBINED CARDIOTOCOGRAPHIC-ELECTROCARDIOGRAPHIC ST (CTG+ST) MONITORING**

CTG+ST monitoring was commercialized in 2000, and combines continuous internal CTG monitoring with continuous 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®, Neovinta, 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 <sup>36,37</sup>. 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 labour, and the display of continuous information.

### **Indications**

CTG+ST monitoring may be used to provide additional information about cardiac oxygenation in cases of suspicious or pathological CTG tracings (see Chapter 3). When reduced variability and absent accelerations are already present on the CTG, ST information cannot be reliably used to indicate fetal hypoxia/acidosis (see below). With pathological CTGs indicating a severe and acute event (see Chapter 3), immediate action should be undertaken with or without the occurrence of ST events.

### **Technique**

A fetal electrode is necessary to acquire continuous CTG+ST signals. Therefore the technique has similar contra-indication to internal CTG monitoring and to FBS (see Chapter 3 or section above on the contra-indications to FBS). The ST technology has not been extensively evaluated in gestational ages below 36 weeks.

### **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<sup>38</sup>. The system's automatic warnings of 'ST events' only occur when it detects changes in ECG morphology when compared to 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 a 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"<sup>39</sup>. 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<sup>38</sup>.

### **Does CTG+ST monitoring improve fetal outcome?**

Six RCTs were published comparing CTG+ST monitoring with isolated CTG, for a total of more than 26 000 enrolled women <sup>40-47</sup>. 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 United States, where a simplified 3-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 because of the different version of the technology <sup>48-52</sup>, and whether a more recent study <sup>52</sup> should be included because its entry criteria contradict the established CTG+ST guidelines.

All five European RCTs point to a reduction of FBS use in the CTG+ST arm of about 40%. 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 + cesarean sections) 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 <sup>47</sup>.

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, reporting progressive declines in the incidence of metabolic acidosis, with stable or decreasing intervention rates <sup>53-55</sup>. 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 labour 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 <sup>56</sup>.

### **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 labour without the occurrence of ST events. Finally, ST events have been reported in about 50% of normally oxygenated fetuses, but only in 16% they were associated with abnormal CTG patterns warranting intervention according to the STAN guidelines <sup>57</sup>.

## **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 (Chapter 3). Over the last two decades, a small number of systems have been commercialised for computer analysis of intrapartum fetal monitoring signals, all in association with fetal central monitoring stations <sup>58</sup>: IntelliSpace Perinatal<sup>®</sup>, incorporating the former OB TraceVue<sup>®</sup> (Philips Healthcare<sup>®</sup>, Eindhoven, Netherlands), Omniview-SisPorto<sup>®</sup> <sup>59</sup> (Speculum, Lisbon, Portugal), PeriCALM<sup>™</sup> <sup>60</sup> (LMS Medical systems, Montreal, Canada and PeriGen, Princeton, USA), INFANT<sup>®</sup> <sup>61</sup> (K2 Medical Systems<sup>™</sup>, Plymouth, United Kingdom), and Trium CTG Online<sup>®</sup> (GE Healthcare<sup>®</sup>, Little Chalfont, United Kingdom 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 <sup>59</sup>. These alerts are aimed at raising attention to specific findings and prompting tracing re-evaluation, with subsequent action if considered necessary. All systems use relatively similar colour-coding of alerts, and they 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, generally yielding satisfactory results <sup>62-66</sup>. 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 <sup>67-69</sup>. 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 multicentre RCTs comparing them with standard CTG analysis <sup>70,71</sup>, and their results are expected soon.

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

## **Conclusions**

There is still a lot of 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 randomised trials, so 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 with 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 labour is the main requisite for intrapartum fetal monitoring, and when repetitive decelerations are present, 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.

### **Conflicts of interest**

Diogo Ayres-de-Campos and João Bernardes are co-developers of the Omniview-SisPorto system. They do not receive funding from commercialisation of the program, but the University of Porto receives royalties which 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 conduction of research on non-invasive electrocardiographic monitoring. Austin Ugwumadu has received honorarium from Neoventa for delivering lectures on fetal monitoring.

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