DOI: 10.1111/1471-0528.12614
www.bjog.org

Commentary

Fetal scalp blood sampling during labour: is it a useful diagnostic test or a historical test that no longer has a place in modern clinical obstetrics?

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Accepted 30 September 2013. Published Online 6 March 2014

Please cite this paper as: Chandraharan E. Fetal scalp blood sampling during labour: is it a useful diagnostic test or a historical test that no longer has a place in modern clinical obstetrics?. BJOG 2014; 121:1056–1062.

Intrapartum continuous electronic fetal heart rate monitoring using a cardiotocograph (CTG) was introduced in the 1960s to identify and respond to intrapartum fetal hypoxia promptly. Unfortunately, CTG was found to have a high false-positive rate of 60% or more.[1] In addition, no significant decrease in the rates of cerebral palsy or perinatal deaths was reported over a 30-year period despite an increase in caesarean section rate.[2]

Fetal scalp blood sampling (FSBS) was advocated as an 'additional test' of fetal wellbeing to reduce the false-positive rate of CTG. The aim was to identify the presence of acidosis (low pH) in a sample of blood taken from the fetal scalp so as to differentiate at least 60% of fetuses who were not hypoxic from 40% of fetuses who were experiencing intrapartum hypoxia when the CTG was classified as 'pathological'. The aim was to avoid unnecessary operative interventions due to the false-positive rate of CTG.

However, FSBS itself has been shown to have a poor positive predictive value for intrapartum hypoxia[3] and recent systematic reviews have reported no evidence of benefit in reducing the operative interventions.[4,5] Hence, practising clinicians need to critically examine whether FSBS is a useful test or just a historical 'outdated' test perpetuated by an obstetric culture, without sufficient scientific and physiological basis to support its use in modern obstetric practice.

Contrary to the popular belief in the UK, FSBS did not develop as an additional test of fetal wellbeing to reduce the false-positive rate of CTG. FSBS developed as a test of fetal wellbeing in its own right, used by Saling in Berlin, Germany in 1962, before commercial production of CTG machines in 1968. He took scalp blood samples from babies during labour to detect acidosis and published his series.[6] This test, which was then developed as an alternative to CTG, was subsequently introduced in the UK, when CTG was found to have a high false-positive rate,[1] to reduce unnecessary operative interventions.

The recommended 'normal' scalp blood pH values were obtained from the original study, which included <80 babies during labour.[6] He recommended that 'if fetal scalp pH is pre-pathological or even pathological (<7.19), fetal blood sampling should be repeated again and if there is a further fall in pH, then delivery should be instituted'. Hence, there was very limited scientific evidence to support the current National Institute for Health and Care Excellence (NICE) recommendation[4] that stipulates an immediate delivery when the FSBS (scalp pH) value is <7.20.

In the UK, an observational study in 1968 erroneously assumed that a 'normal' fetal pH during labour should be between 7.30 and 7.36.[7] Based on this assumption, this author postulated that a pH of <7.25 was suggestive of 'asphyxia'. A closer scrutiny of this study reveals that 'clinical evidence of fetal distress' was made based on the presence of 'meconium' in the amniotic fluid and the study had only 37 babies on the 'fetal distress' arm.[7]

A subsequent large study that included over 15 000 babies, however, concluded that 'normal' fetal pH during labour is skewed to the left, indicating that babies may have a pH of less than 7.20 at birth, even though there is no 'asphyxia'.[8]

Therefore, current normal and abnormal values for fetal scalp pH that were recommended by the NICE Guideline Development Group on Fetal Monitoring[4] were derived from two small studies[6,7] that were performed in 1962 and 1968, without sound scientific basis.

A suspicion of hypoxia and acidosis in adults warrants an arterial blood gas analysis to determine pH and other parameters. Clinicians do not even take a venous sample in adults, although this would be technically an easier procedure to perform. This is because it is an arterial sample that reflects oxygenation of the central organs and not a venous or a capillary blood sample.

In clinical practice, no clinician would ever attempt to take a blood sample from a peripheral tissue (fingertips, toes or indeed the adult scalp) to determine acid–base status as it would be considered useless. This is because, in response to hypoxia, release of catecholamines (noradrenaline and adrenaline) would result in intense peripheral vasoconstriction. Resultant diversion of the oxygen from peripheral tissue (fingertips, toes, scalp) to supply central organs would lead to a 'peripheral acidosis' in all peripheral tissues. This is a normal compensatory mechanism to cope with hypoxia and therefore, testing a peripheral tissue such as the fetal scalp for acidosis reflects a poor understanding of the physiological response to hypoxia.

Pulse oximetry is used to assess oxygen saturation in adults and based on this practice, fetal scalp pulse oximetry was introduced into clinical practice. However, the results are affected by the presence of meconium and blood and a recent Cochrane Review has concluded that fetal pulse oximetry is not associated with improvement in outcomes.[9]

There are no randomised studies comparing FSBS with a sham or no intervention. Randomised studies on FSBS have only compared lactate to pH testing on FSBS,[10] and therefore the safety and effectiveness of the procedure per se versus no such procedure have not been evaluated by level 1 data.

Fetal scalp blood sampling was introduced in 1962, at a time when there was no other means of monitoring fetal wellbeing in labour, other than a Pinard's stethoscope. Fetal scalp was sampled because it was the only accessible fetal tissue during labour from which blood could be taken for analysis. However, during hypoxia, a fetus diverts oxygenated blood from all its non-essential organs (including the scalp) to perfuse its essential organs (brain, heart and adrenal glands). Hence, it does not make much physiological sense to take a sample from a 'nonessential organ' to look for evidence of acidosis during attempts at fetal compensation for ongoing intrapartum hypoxic stress.

Fetal scalp blood sampling looks for changes in pH or lactate in a small sample of blood taken from tissues of the fetal scalp. Therefore, the results are not only influenced by the presence of agents that alter the pH, but also by the site of scalp puncture. There is scientific evidence indicating that taking a scalp blood sample at the site of 'caput' (venous oedema on the fetal scalp) gives rise to more acidotic pH values compared with a sample from a normal area of fetal scalp.[11]

In addition, presence of meconium in the amniotic fluid has been shown to significantly reduce the positive predictive value of FSBS for fetal acidosis.[12] This is because meconium contains bile acids that may alter the pH due to contamination. Presence of normal amniotic fluid itself, which is alkaline, has been shown to significantly alter the FSBS result significantly *in vivo*.[13] In addition, it has been reported that taking a fetal scalp blood sample during a uterine contraction results in more acidotic values than taking scalp blood samples between uterine contractions.[14]

A recent study that compared pH values of paired scalp blood samples concluded that 43% of fetal scalp samples that were obtained from the same fetus at the same time were significantly different and in 16%, this difference crossed the decision threshold for intervention.[15] Therefore, current scientific evidence suggests that FSBS is an unreliable test and its result is influenced by several variables, including contamination with normal amniotic fluid.

One of the great concerns about FSBS is whether a sample of blood that is taken from a peripheral tissue (fetal scalp) accurately reflects oxygenation of central organs. Adamson et al. attempted to demonstrate the correlation between pH of fetal scalp blood sample and pH in the carotid artery and jugular vein in monkeys.[16] Unfortunately, this very small study that included only 11 monkeys and appeared to show such a 'perfect' correlation had several methodological flaws. It was not performed during labour but the mother monkeys were anaesthetised before the onset of labour. Hence, it was very likely that, in the absence of re-distribution of blood from fetal scalp to the brain secondary to ongoing hypoxia, a perfect correlation was demonstrated. In addition, the experimental conditions of this study that included only 11 monkeys did not reflect the physiology of human labour as the monkeys were electively anaesthetised[16]. Moreover, fetal scalp oedema (caput) that adversely affects the results of FSBS[11] was also avoided by this procedure and so the results obtained were not a true reflection of fetal scalp pH that would be seen during normal human labour.

Correlation between fetal scalp pH and umbilical arterial cord pH was carried out by Boenisch and Saling on 119 fetuses and had several unrealistic statements including performing a scalp fetal blood sample exactly 15 minutes before a vaginal birth in all fetuses.[17] It is not biologically plausible to predict the exact time of birth in human labour and therefore, it was very unlikely that all fetuses spontaneously delivered exactly 15 minutes after taking scalp blood samples.

Fetal scalp blood sampling does have a historical importance as it was invented by Erich Saling in Germany when CTG machines were not commercially available. However, it was not designed to be an 'additional test of fetal wellbeing' as is currently used in the UK. There is very limited, if any, scientific evidence to support its use in modern obstet-

Table 1. Fetal scalp blood sampling (FSBS): summary of the studies quoted in the text.

Study	Study design	Details of FSBS	Findings	Clinical implications
Saling et al.[6] No. of subjects: 69	Observational study	Scalp blood samples for taken in 69 babies during first and second stages of labour and a normogram was determined	Normal values were obtained from < 80 babies during labour	A very small study to determine normal values.
Beard et al.[7] No. of subjects: 37	Observational study	Presence of meconium or abnormal CTG was used to make a diagnosis of 'fetal distress'. All babies were delivered by an emergency caesarean section.	This very small study (37 babies) erroneously assumed that the normal fetal pH at birth < 7.25 was indicative of asphyxia	Current recommended normal pH value for FSBS (> 7.25) is based on this erroneous assumption and therefore, needs to be questioned.
Helwig et al.[8] No. of subjects:15,073	Prospective observational study	Blood samples were compared to neonatal outcomes	This large study that included > 15 000 babies concluded that pH < 7.20 was not associated with poor neonatal outcomes	Current recommended normal FSBS value (> 7.25) as well as threshold for intervention (< 7.20) are not based on robust scientific evidence.
Odendaal et al.[11] No. of subjects: 20	Prospective observational study	Fetal scalp blood was taken from an area of caput as well as on the 'non-caput' area and the results were compared	A sample of blood taken from an area of caput significantly differed from a 'normal' area of scalp	FSBS results would be unreliable as the values would depend on the area of scalp that is punctured.
Carbonne et al.[12] No. of Subjects: 174	A prospective multicentre observational study	Fetal scalp pH was compared with fetal pulse oximetry during labour. Cases with meconium staining of amniotic fluid were compared to those with clear amniotic fluid	In the presence of meconium staining of liquor, the positive predictive value of FSBS for intrapartum hypoxia was only 17%	FSBS is unreliable in cases of a pathological CTG in the presence of meconium staining of liquor.
Lösch et al.[13] No. of Subjects 35	*In vitro* experimental study	Scalp venous sample were taken in 35 fetuses during labour and were mixed with respective amniotic fluid samples which were diluted up to ten times in the laboratory	FSBS results are affected by the presence of amniotic fluid as the alkaline amniotic fluid neutralises the acidic pH of the scalp blood.	FSBS may give a falsely reassuring result even if there is ongoing peripheral tissue acidosis, if the sample is contaminated by amniotic fluid
O'Brien et al.[15] No. of Subjects: 293 prospective attempts at FSBS	Prospective observational study	Consecutive paired fetal scalp blood samples were analysed	Analysis of paired scalp blood samples revealed that in 43% both fetal scalp samples that were obtained from the same fetus at the same time were	FSBS results are very unreliable and show a wide variation even if two samples are taken in the same fetus at the same time.

Table 1. (Continued)

Study	Study design	Details of FSBS	Findings	Clinical implications
			significantly different and in 16%, this crossed the decision threshold for intervention	
Schaap et al.[19] No. of subjects: 37	Case report and review of literature	A case of cerebrospinal fluid leakage after fetal scalp blood sampling was described and a literature search was performed to determine the complications.	Serious complications including life-threatening haemorrhage, scalp abscess and drainage of cerebrospinal fluid are associated with FSBS	Use of FSBS without sound scientific evidence may increase the risks without affording any clinical benefits.

ric practice. American College of Obstetricians and Gynecologists guidelines (ACOG) acknowledged decreased use of FSBS in 2009, its most recent review of the topic.[18] Even the NICE Guideline Development Group, after a detailed review of available evidence, conceded that there was no evidence that FSBS reduced incidence of caesarean sections or instrumental deliveries or influenced long-term outcomes.[4] Despite this, NICE recommended its use in the UK based on 'clinical experience' because it was felt that it may reduce 'some' operative interventions. However, a Cochrane Systematic Review that was published 1 year after NICE Guidelines confirmed that FSBS did not reduce caesarean section instrumental vaginal birth rates and did not influence any neonatal outcomes.[5]

A recent review on complications of FSBS reported drainage of cerebrospinal fluid as well as several other rare, but potentially very serious, complications, which included haemorrhage and scalp abscess.[19] In my own medico-legal practice, four cases of serious adverse incidents, including a case with hemiplegia that was directly contributed to by FSBS, were encountered within the last 12 months.

Hence, the NICE Guideline Group that recommended the use of FSBS in clinical practice without any scientific evidence but based on the Guideline Group's individual 'clinical experience' should urgently review their recommendation in the light of current evidence by *Cochrane Systematic Review* and reported serious complications. In the meantime, obstetricians should critically review current scientific evidence pertaining to FSBS before performing this test (Table 1).

Fetal scalp blood sampling had a historical importance in obstetric practice, being introduced when CTG machines were not commercially available. However, there is very limited scientific evidence to support its use in modern obstetric practice and although it is generally considered to be a safe test, it is associated with potentially serious complications. Hence, its continued use in modern obstetric practice without level 1 scientific evidence to support its usefulness should be questioned.

In my opinion, we can no longer justify performing FSBS to 'follow NICE Guidelines' when such guidelines were not based on sound scientific evidence.

Our reluctance to change our culture and historical practices should no longer be an excuse because our primary objective as clinicians should be to 'first do no harm'. Continuing to perform FSBS without scientific evidence may result in risks associated with the procedure without any potential benefit, which may lead to adverse clinical and medico-legal consequences.

Disclosure of interests

EC is the co-organiser of the Intrapartum Fetal Surveillance Course at the Royal College of Obstetricians and Gynaecologists and Fetal Monitoring Courses at St George's University of London. He uses fetal ECG for intrapartum fetal heart rate monitoring and conducts several masterclasses on CTG and fetal ECG in the UK and abroad and is a member of the Editorial Board for NHS e-learning on CTG. He is currently involved in revising the international FIGO Guidelines on CTG.

Contribution to authorship

EC is the sole author.

Details of ethics approval

Not applicable to commentary.

Funding

None.

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Fetal scalp blood sampling: to do or not to do?

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Mini commentary on 'Fetal scalp blood sampling during labour: is it a useful diagnostic test or a historical test that no longer has a place in modern clinical obstetrics?'

Clinical and laboratory investigations are important to further understanding of health and disease. Advances in our knowledge naturally lead to the development of methods to promote health, and to prevent and cure disease. As new knowledge is gained it is important to periodically question if current medical practice is still of clinical value. In this issue of the journal Chandraharan's clinical commentary poses this very question about fetal scalp blood sampling (FSBS) during labour and revision of the National Institute for Health and Care Excellence (NICE) guideline for FSBS (NICE clinical guideline 55. London: NICE; September 2007).

Intrapartum fetal assessment is commonly performed using electronic fetal heart rate monitoring (EFM). Since its introduction EFM has evolved for use in antepartum as well as intrapartum fetal assessment. The nomenclature for fetal heart rate pattern characteristics and the recommendations for interpretation and management have also evolved. More than 80% of labouring women undergo EFM even though there are limitations of 'poor interobserver and intraobserver reliability, uncertain efficacy, and a high false-positive rate' (American College of Obstetricians and Gynecologists [ACOG] Practice Bulletin No.106. *Obstet Gynecol* 2009;114:192–202).

Chandraharan chronicles how two different methods of fetal assessment (EFM and FSBS) came to be used in a complimentary manner. The medical community adopted FSBS as a way to address the high false-positive rate of EFM. In his critical analysis Chandraharan points out that the

studies used to determine normal acid–base status had limitations such as small sample size and questionable criteria of fetal distress. The author makes a compelling argument against the use of FSBS in that a sample of blood from nonessential peripheral tissue (fetal scalp) is being used to assess the acid–base status of essential central organs (e.g. brain, heart). During the stress of hypoxia, blood is normally shunted away from the fetal scalp. This would lead to a 'peripheral acidosis' and provide misleading information. Chandraharan contends that this does not make physiological sense and should not be done in clinical practice. However, there is an example in adult clinical medicine where peripheral tissue assessment is used to provide a non-invasive assessment of oxygenation. Pulse oximetry is widely used to assess the adequacy of a patient's respiratory status in regard to oxygenation. However, unlike in the fetus, an arterial blood gas can verify an abnormal result before additional intervention is undertaken in adults.

The NICE Clinical Guideline No 55 (NICE. September 2007) is a 332-page comprehensive document of intrapartum care. Section 13.6 of the guideline addresses adjuncts to the use of continuous EFM for fetal assessment. One adjunct is FSBS. A critical review of the available data and shortcomings are presented and under limited situations the guideline recommends the use of FSBS. The NICE recommendation is not unlike that made by ACOG. When assessing a persistent Category III tracing a FSBS 'may be considered' (ACOG Practice Bulletin No.106. *Obstet Gynecol* 2009;114:192–202).

Aside from the issue of the robustness of the data about FSBS there are more practical reasons to consider the abandonment of FSBS: (1) non-invasive assessment of the fetus (fetal heart rate acceleration with digital scalp stimulation) can provide assurance about absence of acidaemia, (2) FSBS is limited to those women with sufficient cervical dilation and membrane rupture to access the fetal scalp, (3) the equipment needed for FSBS may not be as readily available on labour units as it had been in the past. This latter reason may be the most important in deciding whether to do or not to do an FSBS. A critical assessment of FSBS is not unwarranted, as called for in this timely commentary.

Disclosure of interests

The author has no conflicts of interest that would pertain to this manuscript.

Research needed before FSBS can be used as a safe and effective screening test

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Mini commentary on 'Fetal scalp blood sampling during labour: is it a useful diagnostic test or a historical test that no longer has a place in modern clinical obstetrics?'

The evidence on fetal scalp blood sampling (FSBS) should be reviewed in the context of what are the criteria for a safe and effective screening test (Table 1), and as it relates to all other screening tests of intrapartum fetal monitoring. Current practice, in particular in developed countries, is to monitor only the fetal heart rate (FHR) by cardiotocography (CTG). The CTG is abnormal (e.g. category III tracing as per the American College of Obstetricians and Gynecologists [ACOG]), for only 1% or less of fetuses of mothers in labour, with up to 70% having category II tracings, a 'grey' zone. This gives FHR monitoring a high – up to 98% – false-positive rate (Nelson et al. *NEJM* 1996;324:613–18). Hence, FHR monitoring is clearly insufficient to assure that all mothers carrying babies who could be safely born vaginally do not receive a caesarean for falsely alarming CTG.

Other screening tests for monitoring fetal wellbeing in labour have been proposed, often as 'ancillary tests' to CTG to try to decrease its false-positive rate, or even to replace it completely. These include FSBS, scalp or vibroacustic stimulation, ST analysis, and fetal oximetry. Each of these tests, to be used in practice, should fulfil the criteria of a safe and effective screening test. The gaps in understanding of the precise pathophysiology of the development of metabolic acidosis during labour hinders the efficacy of all these fetal screening tests.

Fetal scalp blood sampling has not been evaluated in a randomised con-

Table 1. Table 1Criteria for a safe and effective screening test.

Characteristic of screening test	Comments	FSBS fulfils criterium
Disease is clinically important	Fetal metabolic acidosis is associated with mental retardation, cerebral palsy, etc.	Yes
Disease is clearly defined	Metabolic acidosis: pH <7.00 and base excess >12 mmol/l	Yes
Disease prevalence is well known	About 1%	Yes
Disease natural history is known / Recognisable early asymptomatic phase	Fetuses usually start with normal pH and base excess before labour, and can develop metabolic acidosis in labour, but causes and pathophysiology are still unclear	Questionable
Screening technique is well-described	Several articles of the technique of FSBS	Yes
Screening is safe and acceptable	Safety: Serious complications including life threatening haemorrhage, scalp abscess and drainage of cerebrospinal fluid have been reported* Acceptability has not been studied adequately yet, but labouring women experience some pain and stress associated with FSBS	Questionable
Screening has a reasonable cutoff identified	pH <7.20 or lactate >4.8 mmol/l	Yes
Results are reproducible (reliable)	43% of fetal scalp samples from the same fetus at the same time are significantly different, and in 16% this crosses the decision threshold for intervention**	Questionable
Results are accurate (valid)	Poor positive predictive value***	Questionable
'Early' intervention is effective	Caesarean delivery	Yes
Screening and treating 'abnormals' is cost-effective	No cost-effectiveness manuscripts published	Questionable
Facilities for screening are readily available	FSBS kits are not available everywhere (e.g. not available in USA)	Questionable
Facilities for treatment are readily available	Treatment is usually caesarean delivery, which is usually readily available in developed countries	Yes

*Schaap et al. *Obstet Gynecol Surv* 2011;66:42–6; **O'Brien & Murphy *EJOGRB* 2013;167:142–5; ***Clark & Hankins *AJOG* 2003;188:628–33.

trolled trial (RCT) as a primary test against sham or no intervention, with or without CTG or any other intrapartum tests. FSBS has been reported in RCTs only as an ancillary test when evaluating continuous FHR monitoring or ST analysis as primary tests.

There are no RCTs evaluating the safety and efficacy of scalp or vibroacustic stimulation. An acceleration following fetal scalp stimulation indicates that the likelihood of low scalp pH is 2%, and this predictability has been used to attest its utility (Skupski et al. *Obstet Gynecol* 2002;99:129–34).

ST analysis is not associated with significant perinatal benefits in women with nonreassuring FHR on continuous monitoring, compared with no ST analysis. No fetal benefit from ST analysis is observed with proper use of FSBS, and any effect of FSBS is unclear in these trials (Potti & Berghella. *Am J Perinatol* 2012;29: 657–64).

Fetal pulse oximetry is not associated with significant maternal or neonatal benefits compared with continuous FHR monitoring alone (East et al. *Cochrane Database Syst Rev* 2007;2:CD004075).

Fetal scalp blood sampling has only 'questionable' evidence, insufficient to call it a safe and effective screening test, regarding its safety, reproducibility, accuracy, lack of cost-effectiveness studies, and unavailability of kits (Table 1) (Schaap et al. *Obstet Gynecol Surv* 2011;66:42–6; O'Brien & Murphy *EJOGRB* 2013;167:142–5; Clark & Hankins *AJOG* 2003;188:628–33). Similar conclusions can be reached when reviewing the evidence for the other intrapartum fetal monitoring screening tests. Given that fetal scalp pH < 7.20 or lactate > 4.8 mmol/l as detected by FSBS do have some predictability for metabolic acidosis, RCTs are needed to evaluate this modality in algorithms using other screening tests. Perhaps more importantly, better understanding of the pathophysiology of intrapartum fetal metabolic acidosis is needed, with the development of novel tests that are safer and have higher efficacy, fulfilling all criteria of an optimal screening test.

Disclosure of interests

Nothing to disclose.