Evaluating the value of intrapartum fetal scalp blood sampling to predict adverse neonatal outcomes: A UK multicentre observational study

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Abstract: (350)

Objective: To evaluate the value of fetal scalp blood sampling (FBS) as an adjunct test to cardiotocography, to predict adverse neonatal outcomes.

Study design: A multicentre service evaluation observational study in forty-four maternity units in the UK. We collected data retrospectively on pregnant women with singleton pregnancy who received FBS in labour using a standardised data collection tool. The primary outcome was prediction of neonatal acidaemia diagnosed as umbilical cord arterial pH<7.05, the secondary outcomes were the prediction of Apgar scores<7 at 1st and 5th minutes and admission to the neonatal intensive care unit (NICU). We evaluated the correlation between the last FBS blood gas before birth and the umbilical cord blood and adjusted for time intervals. We constructed 2x2 tables to calculate the sensitivity, specificity, positive (PPV) and negative predictive value (NPV) and generated receiver operating curves to report on the Area Under the Curve (AUC).

Results: In total**,** 1422 samples were included in the analysis; pH values showed no correlation (r=0.001, p=0.9) in samples obtained within an hour (n=314), or within half an hour from birth (n=115) (r=-0.003, p=0.9). A suboptimal FBS pH value (<7.25) had a poor sensitivity (22%) and PPV (4.9%) to predict neonatal acidaemia with high specificity (87.3%) and NPV (97.4%). Similar performance was noted to predict Apgar scores <7 at 1st (sensitivity 14.5%, specificity 87.5%, PPV 23.4%, NPV 79.6%) and 5th minute (sensitivity 20.3%, specificity 87.4%, PPV 7.6%, NPV 95.6%), and admission to NICU (sensitivity 20.3%, specificity 87.5%, PPV 13.3%, NPV 92.1%). The AUC for FBS pH to predict neonatal acidaemia was 0.59 (95%CI 0.59-0.68, p=0.3) with similar performance to predict Apgar scores<7 at 1st minute (AUC 0.55, 95%CI 0.51-0.59, p=0.004), 5th minute (AUC 0.55, 95%CI 0.48-0.62, p=0.13), and admission to NICU (AUC 0.58, 95%CI 0.52-0.64, p=0.002)

Forty-one neonates had acidaemia (2.8%, 41/1422) at birth. There was no significant correlation in pH values between the FBS and the umbilical cord blood in this subgroup adjusted for sampling time intervals (r= 0.03, p=0.83).

Conclusions: As an adjunct tool to cardiotocography, FBS offered limited value to predict neonatal acidaemia, low Apgar Scores and admission to NICU.

Funding: None

Keywords: Fetal scalp – Blood sampling – Intrapartum – Accuracy – Acidaemia – Asphyxia

Introduction:

Fetal surveillance in labour is an essential practice in modern obstetric to monitor fetal wellbeing and reduce the risk of adverse neonatal outcomes. Cardiotocography (CTG) remains the primary tool to monitor the fetal heart rate and screen for intrapartum hypoxia, however, due to its low specificity, several adjunct diagnostic tools have been proposed to increase its accuracy.(1) Fetal scalp blood sampling (FBS) is proposed as an objective test to assess the fetal metabolic status in labour, measuring capillary pH and base excess values, thus prompting further interventions when fetal acidaemia is suspected. Still, its effectiveness as an adjunct tool to CTG to improve perinatal outcomes remains uncertain.(2)

In practice, many factors can affect the accuracy of FBS to predict fetal compromise such as sample contamination, failure to obtain samples timely and underlying fetal complications like anaemia and infection.(3) Such limitations call to question the value of using FBS as a gold standard to evaluate the fetal metabolic status (4) especially within the diagnostic thresholds set in current national guidelines.(2) We conducted a multi-centre observational service evaluation study to assess the value of using FBS in labour to predict neonatal acidaemia and associated adverse neonatal outcomes

Methods:

Study design

The study was conducted by members of The UK trainee Audit and Research Collaborative in Obstetrics and Gynaecology (UKARCOG.org). The corresponding author is the study guarantor and assumes responsibility for the completeness and accuracy of the data and analyses, and for the fidelity of the study to the registered protocol.

The study protocol was conceived by the UKARCOG core group and approved by all collaborators. We registered the protocol prospectively with the clinical governance department at each of the participating maternity units. A copy of the protocol is publicly available on the internet (www.UKARCOG.org). Our project was exempt from ethical approval as a service evaluation study collecting data routinely recorded in the National Health Service (NHS).

Participants

We collected data retrospectively on pregnant women with a singleton pregnancy who underwent FBS in labour and had umbilical cord blood gases recorded at birth. We identified participants by screening the logs of blood gas analysers at participating units for paired FBS and umbilical cord blood samples and then linked data to the women's electronic or paper-based clinical notes. Samples with no paired pH values on both the FBS and the umbilical cord blood gas were excluded. Samples with no paired arterial and venous umbilical cord blood gas were also excluded from the analysis.

Outcome measures

The primary outcome was the accuracy to predict neonatal acidaemia defined as an arterial umbilical cord pH value <7.05.(2) The secondary outcomes were the accuracy to predict Apgar

scores<7 at the1st minute and the 5th minute, and admission to the neonatal intensive care unit (NICU). We defined a FBS pH value as normal if it was >7.25, suboptimal if it was 7.25-7.20 and abnormal if it was <7.20. We defined a FBS lactate value as normal if it was <4.2, suboptimal if it was 4.2-4.8 and abnormal if it was >4.8.(2)

We collected data on the: gestation age at delivery, gravidity, parity, duration of 1st and 2nd stages of labour, incidence of maternal pyrexia (>38.0 C°) in labour, incidence of meconium-stained liquor in labour, birth weight, date and time of each FBS sample, cervical dilation at each FBS sample, pH value, base excess value and lactate value on each FBS sample, date and time of birth, birth outcome, mode of delivery, cord blood gas pH, base excess and lactate values, Apgar scores at 1st and 5th minute of life, and admission to the NICU. Low birth weight was defined as <2500g.

Data collection

We collected data using a standardised paper-based data collection tool (Appendix 1). All collaborators were debriefed on the use of the tool and confirmed its face validity. Collected forms were coded, anonymised and entered into a standardised Excel-based database locally at each participating unit. Anonymised data were merged centrally for the purpose of the analysis as per the registered protocol.

Statistical analysis

We used the results of the last FBS before birth and the umbilical cord blood gas test values to construct 2x2 tables and calculate the sensitivity, specificity, positive predictive value

(PPV) and negative predictive value (NPV) for each of the following test thresholds to predict the primary and secondary outcomes: suboptimal pH, abnormal pH, suboptimal lactate and abnormal lactate. We generated receiver operating characteristic curves for these test thresholds and reported on the Area Under the Curve (AUC) with 95% confidence intervals (CI) to predict adverse neonatal outcomes with lower test values indicating a more positive test. We used Pearson and partial correlation tests to evaluate the correlation between the pH values on the FBS and the umbilical cord blood samples adjusted for sampling time intervals . We performed a multivariate logistic regression modelling to determine factors affecting the accuracy of FBS and reported using relative risk (RR) and 95%CI on the association between each FBS pH threshold and relevant maternal and neonatal adverse outcomes. All statistical analyses were performed in SPSS v20 (IBM Corp. Armonk, NY).

Results

General findings

We collected data on 1670 women who received a FBS in labour, sample dates ranged between January 2016 and May 2018. We excluded 248 records due to incomplete data, and included 1422 in the analysis. FBS was performed twice in 373 women, three times in 59, and four times in 17 women.

The median gestation age was 40+3 (range 34+2 - 42+1), and the median birth weight was 3405 (range 1940 - 5050). Labour was induced in two-thirds of women (59.6%, 844/1422) and 20% had a normal vaginal delivery (20.4%, 297/1421). Almost half of the included women were delivered via emergency caesarean section (43.1%, 613/1421) and 36% had a vaginal

instrumental delivery (35.6%, 507/1421). The incidence of maternal pyrexia in labour was 10.7% (153/1422) and meconium stained liquor was diagnosed in 18.9% (269/1422). Only 10.4% of neonates had a low birth weight <2500g (10.4%, 148/1422). (Table 1)

A total of 296 fetuses had an Apgar scores <7 at 1st minute (296/1422, 20.8%) and 69 had a scores <7 at the 5th minute (69/1422, 4.8%). Only 8% needed admission to NICU (118/1422, 8.2%). A quarter of fetuses had a suboptimal pH (<7.25) on the last FBS test before birth (12.9%, 184/1422) and 77 had an abnormal pH (<7.20) (5.4%, 77/1422). Lactate was only available in 187 FBS tests and was suboptimal (>4.2) in 31 fetuses (16.5%, 31/187) and abnormal in 23 (12.2%, 23/187).

Overall there was poor correlation between FBS blood markers and those on the umbilical cord (pH r= 0.22, p=0.001; BE r= 0.36 p=0.001; Lactate r=0.23, p=0.002). We evaluated the correlation between the pH values of the FBS and the umbilical cord arterial blood gas in samples performed within an hour from birth and adjusted for sampling time intervals. There was no significant correlation (r=0.001, p=0.9) in pH values in samples obtained within an hour (n=314) from birth, or in those within half an hour from birth (n=115) (r=-0.003, p=0.9).

A suboptimal FBS pH value (<7.25) had a poor sensitivity (22%) and PPV (4.9%) to predict neonatal acidaemia with high specificity (87.3%) and NPV (97.4%). Similar performance was noted to predict Apgar scores <7 at 1st (sensitivity 14.5%, specificity 87.5%, PPV 23.4%, NPV 79.6%) and 5th minute (sensitivity 20.3%, specificity 87.4%, PPV 7.6%, NPV 95.6%), and admission to NICU (sensitivity 20.3%, specificity 87.5%, PPV 13.3%, NPV 92.1%) (Table 2). Similarly, an abnormal FBS pH (<7.20) had low sensitivity (7.3%) and PPV (3.9%) and high

specificity (94.6%) and NPV (97.2%) for neonatal acidaemia with similar performance to predict the remaining adverse neonatal outcomes (Table 2).

Our ROC analysis revealed a modest performance for FBS pH to predict neonatal acidaemia with an AUC of 0.59 (95%CI 0.59-0.68, p=0.3) (Figure 1) and similar performance for predicting Apgar scores <7 at 1st minute (AUC 0.55, 95%CI 0.51-0.59, p=0.004), 5th minute (AUC 0.55, 95%CI 0.48-0.62, p=0.13), and admission to NICU (AUC 0.58, 95%CI 0.52-0.64, p=0.002). (Table 2) (Appendix 3)

Neonatal acidaemia was diagnosed in 41 neonates (2.8%, 41/1422). Over half of those neonates had an Apgar score <7 at the 1st minute (63.4%, 26/41), 6 had a score <7 at the 5th minute (14.6%, 6/41), and 7 required admission to NICU (17%, 7/41) (Table 1). Twenty were delivered via an emergency caesarean section (20/41, 48.7%) and 13 via an instrumental vaginal delivery (13/41,31.7%). FBS was conducted in the second stage of labour in 10 of these foetuses (10/41, 24.3%). There was no significant correlation in pH values between the FBS and the umbilical cord samples in this subgroup adjusted for sampling time intervals (range 15-462 minutes) (r= 0.03, p=0.83), similar findings were found for BE (r=0.29, p=0.08). Paired Lactate samples were available in only five cases in this subgroup.

Due to the small sample size of paired pH and lactate (n=187), we were unable to accurately evaluate the performance of suboptimal and abnormal FBS lactate to predict the primary and

secondary outcomes. Overall lactate showed a similar performance to pH with high specificity and NPV and low sensitivity and PPV for all adverse neonatal outcomes (Appendix 2).

Associated factors

Women with a suboptimal FBS pH had a RR of 1.62 (95%CI 1.42-1.83) to receive an emergency caesarean section. A similar risk was reported for those with an abnormal FBS pH (RR 1.82, 95%CI 1.58-2.10). Repeating the FBS three or more times in labour was associated with a RR of 1.22 for receiving an emergency caesarean section (95%CI 0.95-1.57). There was no significant association between the FBS pH value and the diagnosis of maternal pyrexia (BE -.246, p=0.37), the diagnosis of meconium stained liquor in labour (BE -.119, p=0.55) or the mode of delivery (vaginal vs emergency caesarean section BE 0.298, p=0.058). There was a negative association with low birth weight (BE -.461, p=0.045).

Discussion

Summary of findings

Our study suggests an overall limited value for using FBS as an adjunct test to CTG to predict adverse outcomes in fetuses at risk of intrapartum asphyxia. FBS pH demonstrated high specificity and negative predictive value to predict neonatal acidaemia, thus, it is a good test to rule out uncompromised fetuses with an abnormal CTG test, but not to rule in those at risk.

Women who had a suboptimal or abnormal FBS pH value had a higher risk of receiving an emergency caesarean section, however, we were not able to record the indication for delivery in

all cases. Interestingly, only a small number of babies delivered via an emergency caesarean section were found to have marked neonatal acidaemia (20/659, 1.4%). This comes in line with evidence suggesting that using FBS did not reduce the rate of emergency caesarean section as hoped.(5) FBS pH values did not correlate with those on the umbilical cord within an hour of delivery or in those neonates with acidaemia at birth, suggesting a limited value of using FBS to aid decision making in labour with a modest AUC for predicting all adverse neonatal outcomes ranging from 0.55 to 0.59.

Strength and limitations

We collected data from 44 maternity units which provide a pragmatic national perspective on the current use of FBS in the NHS. We registered our protocol prospectively at each participating maternity unit and used a standardised data collection tool to reduce performance bias. We obtained a large and diverse sample, though interestingly many women were induced (60%) and only a fifth had a normal vaginal delivery (20%). This could support an association between using FBS and increased risk in labour leading to higher rate of interventions.

Our findings are not without limitations, we collected data retrospectively across multiple sites to obtain a large sample and improve the study power, , however, we could not obtain consecutive cases across all sites The practice of FBS is standardised across the NHS and reported outcomes are collected routinely in standardised maternity records as per established national guidelines. We, therefore, do not perceive significant variation in data collection. We did not record the indication for performing the FBS and presumed it to follow an abnormal intrapartum CTG. Variations in CTG interpretations, prompting FBS testing, are likely and our findings should be

interpreted pragmatically. Our study design is subject to the treatment paradox, interventions to prompt early delivery and neonatal resuscitation at birth are likely to mend the metabolic status of compromised neonates, thus improving their umbilical cord pH values. Performing in utero resuscitation such as change in maternal position and use of tocolytics could also change the fetal metabolic status from time of FBS to time of birth. We planned to adjust correlation testing for sampling time intervals between the last FBS and time of birth. However, our data suffered from high loss of times recorded and we could only adjust in samples within an hour of birth.

We aimed to collect data from all maternity units in the UK, but several units withdraw due to low numbers of FBS tests performed per year. We collected a limited number of samples where FBS lactate was recorded which reduced our ability to accurately evaluate its predictive value.

Implication for clinical practice

The primary aim of using FBS is to improve the detection of intrapartum hypoxia and reduce unnecessary interventions when a CTG is judged to be abnormal. Due to its limited specificity, using CTG as the sole fetal surveillance tool could increase the rate of unnecessary caesarean sections and the associated adverse neonatal and maternal outcomes.(5) Our findings support the ability of a normal FBS pH to reassure health professionals and mothers on the safety of a fetus with an abnormal CTG. However, a suboptimal or abnormal pH using current thresholds seems of limited value to guide further action. This echoes the findings of similar studies confirming the limited value of FBS pH to aid decision making in intrapartum care.(6) Adopting a more comprehensive evaluation of the fetal metabolic status using BE and Lactate in addition to pH could offer better guidance to clinicians.(7)

The current national guideline in the UK recommends performing a FBS when a CTG is judged to be 'pathological'.(2) However, with many diagnostic criteria used to classify and interpret CTG in labour, the poor inter/intra-rater reliability could lead to excessive use of FBS. Some CTG features are considered more abnormal than others (2,8,9), evaluating the correlation between certain CTG features and the findings on the FBS capillary pH could offer better guidance on if and when FBS is warranted. Developing a deeper understanding of the fetal pathophysiology and the fetal response to intrapartum hypoxic stress may obviate the need for FBS.(10)

Current guidance supports the validity of FBS predictive value for an hour in the first stage of labour and half an hour in the second stage.(2) However, there is limited evidence on the longitudinal changes in pH values in labour. This was evident in our sample with no apparent correlation in pH values within an hour from birth. Khuehle et al presented better correlation in pH value within an hour from birth (6), though their findings did not adjust for sampling time intervals. Clearly, the depreciation rate in the fetal pH during intrapartum hypoxic stress depends on the individual reserve of the fetus, the rapidity and the intensity of intrapartum hypoxia. Therefore, from a pathophysiological point of view, having 'arbitrary' cut offs (60 minutes or 30 minutes) to obtain new samples appears illogical. A threshold for the maximum number of repeated FBS samples in labour remains unknown. Recent evidence suggested that repetitive fetal blood sampling may double the caesarean section rate (11) which is consistent in our findings with a RR of 1.62 .

The use of capillary lactate seems to offer an easier and more versatile test with reduced failure rate to obtain a sample.(12) Our sample was not sufficient to evaluate its performance as a

predictive test and more research is needed to evaluate its role in modern obstetrics. Several studies reported better correlation in Lactate values between FBS and cord samples (13,14), still no evidence in improving neonatal or maternal outcomes was noted in two randomised trials. (15)

Future research

To date, many adjunct tests to CTG have been proposed to aid the diagnosis of intrapartum hypoxia.(12) While several meta-analyses evaluated their efficacy,(12) there is limited evidence on their accuracy as predictive tools in everyday practice.

The current technology employed to obtain fetal capillary blood is largely undeveloped since its introduction in 1960.(10) Improving the sample acquisition process might increase the FBS accuracy and effectiveness by reducing sample collection failure and contamination.(4) The use of FBS pH should be critically reviewed in the light of our findings, and recent evidence advocating the value of fetal scalp stimulation to provide better information with on fetal wellbeing.(16) Fetal surveillance is a complex intervention with many confounding factors such as the availability of trained staff and the complexity of associated maternal co-morbidity in labour. Evaluating the efficacy of fetal surveillance tools in randomised trials offers a snapshot evaluation of a standardised practice during the lifetime of the trial.(17) Thus, larger effectiveness and longitudinal multicentre follow-ups studies are needed to draw more accurate conclusions and contrast the benefit of using these tools to improve short and long-term neonatal and maternal outcomes.

Conclusion: As an adjunct tool to cardiotocography, FBS offered limited value to predict neonatal acidaemia, low Apgar Scores and admission to NICU.

Acknowledgement:

- The authors appreciate with great gratitude the input of Mr Edwin Chandraharan - Consultant Obstetrician and Gynaecologist at St. George's NHS Trust- who critically reviewed and improved our manuscript.
- The trainees of the UKARCOG network appreciate the help and guidance received from consultants on the RCOG academic board and participating NHS maternity units to accomplish this study.

Funding: None

Disclosure of interest: All authors have nothing to declare

Contribution to authorship:

Bassel H.Al Wattar conceived the idea, wrote the first protocol and manuscript, analysed the data and acted as the study chief investigator. William Parry smith, Nicola Tempest, Mathew Prior, Jennifer Tamblyn, Jonathan Frost and Emma Long revised the protocol and acted as the study management committee. All remaining co-authors actively collected data, oversaw the study conduct and contributed critically to the final manuscript.

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