Accuracy of fetal scalp blood sampling to detect intrapartum fetal acidemia

AB-FAB

Study Protocol

Introduction:
The use of fetal scalp blood sampling (FBS) has been proposed as an intrapartum diagnostic test to detect fetal hypoxia in practice since the 1960s. (1) FBS is mainly used as an adjunct confirmatory tool to compensate on the low predictive value of the cardio-toco graphic monitoring (CTG) and provide an objective evidence of fetal acidemia and the fetal gas exchange status. (2) The accuracy of FBS to capture fetal acidemia remains uncertain, (3) limiting its role in reducing unnecessary interventions and improving neonatal outcomes. (4) This is further complicated by the difficulty in obtaining an appropriate sample in a timely fashion, and the various confounding factors that can affect the quality of FBS results such as fetal infection and meconium contamination.

Performing FBS requires perquisite skills and appropriate settings; failed FBS testing can contribute to raising the caesarean section rate. Furthermore, occasional serious complications can occur after FBS such as cerebrospinal fluid drainage, infection and scalp haematoma.(1) A number of substitutes have been suggested to FBS such as fetal scalp electrodes and fetal ECG, however, they remain limited in practice for various reasons such as training and cost (5).

There is a need to objectively assess the value and accuracy of FBS as an intrapartum test to monitor fetal wellbeing and detect fetal acidemia within existing UK practice.
Aim:
To evaluate the use of FBS as a diagnostic tool for intrapartum fetal acidemia and asphyxia.

Research Questions:

1. How accurate is FBS to diagnose fetal academia?
   a. Does fetal scalp pH correlate to cord pH (venous and arterial)?
   b. Does fetal scalp BE correlate to cord BE?
   c. Does fetal scalp lactate correlate to cord lactate?
   d. What is the ROC curve to diagnose intrapartum fetal academia using fetal scalp PH?

2. Can FBS predict adverse neonatal outcomes (admission to NICU and Apgar scores)?

3. What factors could affect the accuracy of FBS?

Methods:

Design
Large prospective/retrospective multi-center observational cohort study

Setting
Maternity units across the UK performing fetal scalp blood sampling as routine practice.

Inclusion criteria
All pregnant women who:
- Underwent at least one FBS test in labour AND umbilical cord gas test postnatally.
Outcomes

Primary outcome: Fetal PH value on the FBS and umbilical cord gases (venous and arterial).

Secondary outcomes: Base excess and lactate values on FBS and umbilical cord gases. Admission to neonatal unit (irrespective of time spent on the unit), Apgar scores (at 1 and 5 minutes postnatally), birth weight, gestation age at delivery, onset of labour, length of labour, number of FBS tests performed, time of each FBS test, time of delivery, meconium status, presence of maternal pyrexia in labour.

Data collection:

The study will be coordinated by the UKARCOG. Local approval will be sought at each maternity unit (clinical governance unit) and the study protocol will be registered online with public access (clinicaltrials.gov). The study will be registered as a service evaluation capturing data recorded as part of routine practice in the NHS, therefore, exempt from ethical approval.

Patients will be identified from the unit fetal blood gas machine user log or prospectively by the oncall clinical staff. Data will be collected from patients notes (electronic or paper based) in accordance with each local unit policy. A standardised paper based data collection tool will be used including patient’s unit number. No other identifiable will be recorded and all data will be anonymised locally.
Collected forms will be stored safely at regional level by each UKARCOG regional representative until the end of the study. Once data collection is complete, all data will be coded, and entered into an electronic data base by each regional representative using unique study identifiable codes for each participant. Data will be stored safely at a secure NHS owned server for 5 years after completion of the study in compliance with the principles of Good Clinical Practice. No patient identifiable information will be published. The study will not introduce a new intervention or change in standard care provision for patients, thus no individual consent will be sought.

**Statistical analysis:**

Data will be analysed to determine the accuracy of FBS to diagnose fetal acidemia compared to umbilical cord gases as the golden standard. Sensitivity, specificity, positive and negative predictive values will be calculated for primary and secondary outcomes. ROC curves will be constructed and the Area Under the Curve calculated. Threshold values will be recommended taking into consideration both sensitivity and specificity. Correlation and agreement testing will be assessed between scalp and cord gases value for PH, Base excess and Fetal lactate where possible.

Multivariate logistic regression modelling will be conducted where possible to determine factors affecting the accuracy of FBS to diagnose fetal acidemia. Trends in using FBS will be reported in means and percentages. Non-parametric data will be transformed if needed.

**Sample size:**

We estimate the prevalence of acidemia to be 10% of all performed FBS with variations between recruiting sites. We expect no loss to follow up as all data is recorded electronically at each maternity units by default. Assuming a sensitivity and specificity of 90% with a precision of +/- 5%
with 95% confidence intervals we will need to collect data on 4814 cases FBS.

**Ethics:**

Our study qualifies for ethics exemption under a category outlined in the UK Health Departments’ Governance Arrangements for Research Ethics Committees (REC). Research limited to secondary use of information previously collected in the course of normal care is generally excluded from REC review. This exception also applies to research undertaken by staff within a care team using information previously collected in the course of care for their own patients. (7)

**Reporting results:**

The UKARCOG is responsible for analysing and reporting the data in peer-reviewed pubmed cited medical journals. All trainees contributing actively to this work will be nominated collaborators. Authorship will follow the ICMJE guidelines. Where possible, open access publication will be sought subject to funding availability. The study findings will be disseminated though venues of interest such as RCOG congresses to maximise impact.

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References:
1- Chandraraharan, E. (2014). 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: An International Journal of Obstetrics & Gynaecology, 121(9), 1056-1062.