Measurement of fetal scalp lactate to determine fetal well being in labour

Clinical question

Among women at term in labour is the measurement of fetal scalp lactate superior to fetal scalp pH in predicting adverse fetal/newborn outcomes and successful acquisition of a usable sample?	
Population:	Women at term in labour
Intervention:	Fetal assessment using fetal scalp lactate
Comparison:	Fetal assessment using fetal scalp pH
Primary Outcome: Secondary Outcomes:	Apgar scores at 5 minutes Hypoxic ischemic encephalopathy Admission to NICU Umbilical cord arterial pH < 7 Umbilical cord arterial base deficit > 12

Search strategy

- Time period: 1995 -2012
- Search terms: fetal, scalp, lactate, pH, labour.
- Inclusions: meta-analysis, systematic reviews, randomized controlled trials, cohort studies,
- Databases searched: CINAHL; MEDLINE (Ovid SP and PubMed); EMBASE; Cochrane CDSR, CENTRAL, & DARE, Google Scholar.
- Titles reviewed – 250; abstracts reviewed – 39; papers reviewed – 14; papers meeting eligibility for inclusion – 12

Synthesis of the evidence

Randomized controlled trials of fetal scalp lactate vs. fetal scalp pH for assessment of fetal well-being in labour indicate that there are no statistically significant differences in Apgar scores at five minutes, admission to a NICU, or hypoxic ischemic encephalopathy.

There are no statistically significant differences in rates of umbilical artery cord pH < 7 or base deficit > 12 mmol/L.

There were significantly higher sampling success rates for scalp lactate samples compared to sampling for scalp pH testing. One trial reported significantly less time required for the procedure for fetal scalp lactate vs. fetal pH sampling.

Prospective cohort studies examining correlations between fetal scalp lactate samples and cord blood report significant correlations with lactate, pH, and base deficit in umbilical cord arterial and venous blood, and with scalp pH.

Limitations

There is no universally accepted level of fetal scalp lactate which is denoted as abnormal. Studies have reported values ranging from 4.2 - 5.4 mmol/L as optimizing prediction of adverse neonatal outcomes. Research to date on fetal scalp lactate testing has primarily involved the Lactate Pro device which is no longer available. Health Canada has recently approved the Statstrip Lactate (Nova Biomedical) for point of care testing of scalp lactate but clinical cut-offs for the Statstrip Lactate have yet to be determined.

Conclusions

Measurement of fetal scalp lactate is equivalent to fetal scalp pH for clinical decision-making to avoid adverse neonatal outcomes. Fetal scalp lactate sampling requires less time and is associated with fewer failed sampling attempts. Further research is needed to determine optimal values to indicate risk for neonatal morbidity.

Meta-analysis	Inclusion	Intervention	Findings	Comments
East CE, Leader LR, Sheehan P, Henshall NE, & Colditz PB. Cochrane Database Syst Rev, 3. 2010;(3):CD006174. **Intrapartum fetal scalp lactate sampling for fetal assessment in the presence of a non-reassuring fetal heart rate trace.**	2 RCTs • Westgren 1998 • Wiberg-Itzel 2008 n = 3348	Randomized to either fetal scalp lactate or pH assessment in labour.	**Primary Outcomes** No statistically significant differences for fetal scalp lactate vs. pH: • Neonatal encephalopathy RR 1.0 (0.32-3.09) • Neonatal death RR 0.14 (0.01-2.76) **Secondary Outcomes** • Low Apgar score at five minutes with testing done within 30 minutes of delivery RR 0.99 (0.57-1.72) • Admission to NICU RR 1.02 (0.83-1.25) • Umbilical arterial pH <7, sample within 60 minutes of delivery RR 0.68 (0.29-1.58). • Metabolic academia (UA pH<7.05 + base deficit >12 mmol/l) sampled within 60 minutes of delivery RR 0.93 (0.52-1.65). There was a statistically higher success rate for lactate sample collection compared with scalp pH risk ratio 1.10 (1.08 to 1.12)	

Randomized controlled trials	Inclusion	Intervention	Outcomes	Comments
Holzmann M, Cnattingius S, & Nordstrom L. Journal of Perinatal Medicine, 2011;39(5):545-548. Sweden University Hospital **Outcome of severe intrapartum acidemia diagnosed with fetal scalp blood sampling**	Scalp lactate (n =89) Scalp pH (n=65) • Singleton pregnancy • Cephalic presentation • Gestational age ≥34 weeks • Non-reassuring fetal heart rate trace	Fetal scalp lactate vs. pH.	**Primary Outcomes** No differences in outcomes • Cord artery pH < 7.00, scalp lactate vs. pH, 9.4% vs. 5.8%, p=0.41 • Apgar < 7 at 1 min, 32.9% vs. 44.9%, p=0.93 • NICU admission, 29.4% vs. 26.1%, p=0.65 • HIE 2.4% vs. 2.9%, p = 0.83. • Delivery was expedited more rapidly in the pH management group (median 16 vs. 21 min; p = 0.01).	The authors state that in view of similar neonatal outcomes in the two groups, the findings of longer time interval between fetal scalp lactate vs. pH sampling and delivery lend support to the opinion that lactate analysis is an earlier marker than pH in the hypoxic process.
Wiberg-Itzel E, Lipponer C, Norman M, Hansson A, Bryngelsson AL, Christoffsson M, Sennstrom M, Wennerholm UB, Nordstrom L, BMJ, 2008;336(7656):1284-1287. Sweden Ten labour wards in Sweden participated between 2002-2005 **Determination of pH or lactate in fetal scalp blood in management of intrapartum fetal distress: randomized controlled multicentre trial**	Scalp pH (n = 1496) Scalp lactate (n = 1496) • Singleton fetus • Cephalic presentation • Gestational age ≥34 weeks • Non-reassuring fetal heart rate trace	Fetal scalp lactate vs. scalp pH.	**Primary Outcomes** No significant difference in the rate of metabolic acidemia. defined as pH < 7.2 and lactate > 4.8 mmol/L, RR 0.91 (0.61-1.36). Cord artery pH < 7.00 RR. 0.84 (0.47-1.50). **Secondary Outcomes** Apgar < 7 at five minutes, RR 1.15 (0.76-1.75) CS for fetal distress RR 1.02 (0.93-1.11) Significantly higher failure rate with pH determination 10.4% vs. 1.2% (lactate).	

Randomized controlled trials	Inclusion	Intervention	Outcomes	Comments
Westgren M, Kruger K, Ek S, Grunevald C, Kublickas M, Naka K, Wolff K, Persson B. British Journal of Obstetrics and Gynaecology, 1998; 105(1):29-33. Sweden Collected at Huddinge University Hospital, Stockholm **Lactate compared with pH analysis at fetal scalp blood sampling: a prospective randomized study**	pH group (n = 169) Lactate group (n = 172) Ominous fetal heart rate patterns	Fetal scalp lactate vs. pH.	**Primary Outcomes** (lactate vs. pH) - no significant differences Apgar < 7 at 1 min: 26% vs. 28% Apgar < 7 at 5 min: 4% vs. 4% NICU admissions: 18% vs. 16% Cesarean Section: 20% vs. 17% Umbilical artery pH <6.98: 4% vs. 8% Umbilical artery base deficit < 19.2: 1% vs .3% **Secondary Outcomes** Fetal scalp incisions per sampling attempt: median 1 vs. 2 Time required for sampling procedure median 120s vs. 230s Fetal blood sampling failures (pH vs. lactate) 42% vs. 2%; OR 16.1 (5.8 - 44.7)	Maternity ward where study was conducted was a referral unit for high risk pregnancies.
Prospective cohort	**Inclusion**	**Intervention**	**Outcomes**	**Comments**
Borruto F, Comparetto C, Treisser A. Archives of Gynecology and Obstetrics 2008; 278:17-22. Italy **Prevention of cerebral palsy during labour: role of foetal lactate**	n = 188 Inclusion criteria not stated	Comparison of fetal scalp lactate and lactate in umbilical artery cord blood.	**Primary Outcome** Scalp lactate correlated significantly with umbilical artery lactate (r = 0.49, p = 0.01), but with neither Apgar score at 1 min (r = 0.21, ns) nor at 5 min (r = 0.11, ns).	

Prospective cohort	Inclusion	Intervention	Outcomes	Comments
Kruger K, Kublickas M, Westgren M Obstetrics & Gynecology 1998;92:918-922. Sweden University Hospital 1995-1996 **Lactate in Scalp and Cord Blood From Fetuses With Ominous Fetal Heart Rate Patterns**	n = 103 Ominous fetal heart rate patterns	Fetal scalp lactate sampled within 60 minutes of delivery, compared to lactate in the umbilical artery and venous lactate, pH and base excess.	**Primary Outcome** Fetal scalp lactate significantly correlated to lactate levels in the umbilical arterial blood ($r = 0.65$, $p < 0.001$) and venous blood ($r = 0.62$, $p < 0.001$). Fetal scalp lactate significantly correlated with pH in arterial ($r=0.28$, $p<0.01$) and venous ($r=-0.46$, $p<0.001$) cord blood. Fetal scalp lactate significantly correlated with base excess in arterial ($r=0.26$, $p<0.01$) and venous (43, $p<0.001$) cord blood.	Authors conclude that high correlations of lactate in scalp blood with arterial and venous cord blood confirm that fetal scalp blood lactate values reflect levels in central fetal circulation.
Nordstrom L, Ingmarsson I, Kublickas M, Persson B, Shimojo M, Westgren, M. BJOG:1995;102:894-899. Sweden Labour wards at University Hospitals of Huddinge and Lund and County Hospital of Ostersund, **Scalp blood lactate: A new test strip method for monitoring fetal wellbeing in labour**	Fetal scalp lactate (n = 269), pH (n = 285) Abnormal intrapartum cardiotocography trace	Fetal scalp lactate vs. fetal scalp pH, cord artery lactate.	**Primary Outcome** Scalp lactate significantly correlated with fetal scalp pH ($p < 0.001$) and umbilical artery lactate ($p < 0.01$).	Within subject comparisons.

Prospective cohort	Inclusion	Intervention	Outcomes	Comments
Allen R, Bowling F, Oats J. Australian and New Zealand Journal of Obstetrics and Gynaecology,2004; 44:549-55. Australia Mater Mothers' Hospital, Brisbane, **Determining the fetal scalp lactate level that indicates the need for intervention in labour**	n = 140 Suspicious or pathological cardiotocography trace	Establish the scalp lactate level in the first stage of labour that indicates the need for intervention.	**Primary Outcome** Optimal sensitivity and specificity for fetal scalp lactate to predict adverse fetal outcomes. • To predict an Apgar of < 7 at 1 min, the scalp lactate level was 4.1 mmol/L. • To predict an arterial cord pH of < 7.20, the scalp lactate level was 4.2 mmol/L. • The predictive scalp lactate level for meconium stained liquor was 4.1 mmol/L	Using receiver operating characteristic curves for sensitivity/ specificity fetal scalp lactate of ≥ 4.2 mmol/L was considered a reasonable predictor of adverse outcomes.
Ramanah R, Martin A, Clement MC, Maillet R, Riethmuller D. Fetal Diagnosis and Therapy 2010;27:14-19. France Conducted from 2003-2007 in the Labour ward of Besancon University Medical Centre, **Fetal scalp lactate microsampling for non-reassuring fetal status during labour: a prospective observational study**	n = 358 (450 fetal scalp blood samples) • Single fetus • Cephalic presentation • ≥ 37 weeks gestation • Abnormal fetal heart rate patterns	Fetal scalp lactate vs. fetal cord blood gas parameters	**Primary Outcome** Scalp lactate correlated significantly with the following: • scalp pH (r = -0.56, p = 0.001) • umbilical artery pH (r = -0.39, p = 0.03) • umbilical artery base deficit (r = 0.48, p = 0.01) However, Apgar scores did not correlate to scalp lactate samples.	Using receiver operating characteristic curves a scalp lactate cutoff of 5 mmol/L was determined to have maximum sensitivity and specificity for neonatal asphyxia.

Prospective cohort	Inclusion	Intervention	Outcomes	Comments
Ramanah R, Martin A, Riethmuller D, Maillet R, Schaal J. Gynécologie, obstétrique & fertilité 2005 ;33:107-112. France Collected from 2001 – 2004 at Maternity Hospital of Besancon **Value of fetal scalp lactate sampling during labour: a comparative study with scalp pH**	n = 129 Fetal heart rate abnormalities	To compare scalp lactate vs. scalp pH, neonatal cord blood gas, and Apgar score.	**Primary Outcome** Scalp lactate correlated significantly with: • Scalp pH (r = -0.54, p = 0.001) • UA cord pH (r = -0.46, p = 0.01) • UA cord lactate (r = 0.49, p = 0.01) Scalp lactate and pH was not significantly correlated with: • Apgar score < 7 at 1 min (r = -0.21, ns) • Apgar score < 7 at 5 min (r = -0.11, ns) Scalp lactate failure was 1% vs. 8% for scalp pH, as more blood was required for pH testing.	The cutoff of > 5 mmol/L for scalp lactate was comparable to scalp PH < 7.20 for predicting acidosis in the umbilical cord artery or lactate > 6.35 mmol/L. The specificity of the scalp lactate was 92.1% for predicting UA pH < 7.10 and 95.4% for predicting UA > 6.35 mmol/L.
Retrospective cohort	**Inclusion**	**Intervention**	**Outcomes**	**Comments**
Kruger K, Hallberg B, Blennow M, Kublickas M, Westgren M. American journal of obstetrics and gynecology 1999;181:1072-1078. Sweden Collected between 1993-1995 from Huddinge University Hospital, Stockholm, **Predictive value of fetal scalp blood lactate concentration and pH as markers of neurologic disability**	n = 814 All patients with ominous fetal heart rate patterns	To compare the ability of fetal scalp lactate vs. pH to predict Apgar scores < 4 at 5 min, and hypoxic-ischemic encephalopathy (HIE)	**Primary Outcome** Using a cutoff of 4.8 mmol/L scalp lactate was more sensitive than scalp pH in predicting Apgar of < 4 at 5 min (58.3 vs. 30.0%) and HIE (66.7 vs. 50.0%). The areas under the receiver operating characteristic curves were significantly higher for the lactate concentration than for the pH value: Apgar score <4 at 5 minutes (p = 0.033) and moderate to severe HIE (p = 0.015).	

Retrospective cohort	Inclusion	Intervention	Outcomes	Comments
Heinis A, Spaanderman M, Klein Gunnewiek J, Lotgering F. Acta Obstetricia et Gynecologica Scandinavica (2011);90:1107-1114. Stockholm , Sweden Conducted in the labour ward of the Radboud University Nijmegen Medical Centre. **Scalp blood lactate for intra-partum assessment of fetal metabolic acidosis**	n = 486 • >34 weeks GA • Singleton fetus • Vertex presentation	Correlation of fetal scalp blood lactate during labor with fetal scalp pH and base deficit, and metabolic acidosis at birth. To determine lactate cut-off values to serve as indicators for immediate intervention.	**Primary Outcomes** Fetal scalp lactate correlated better with metabolic acidosis (UA pH <7.05 and base deficit > 12mmol/l) than fetal scalp pH or base deficit. Fetal scalp lactate concentration correlated with: • UA Cord pH (r = -0.50, p < 0.001) • UA Cord base deficit (r = 0.48, p<0.001) Cutoffs for fetal scalp lactate: • < 5.4 mmol/l indicated reassuring fetal status • lactate ≥ 6.6 mmol/L indicated metabolic acidosis.	Authors note that these lactate cut-off values were estimated in the absence of standard calibration techniques between laboratories and devices, their absolute values are valid only with the Rapidlab-860.