Determination of pH or lactate in fetal scalp blood in management of intrapartum fetal distress: randomised controlled multicentre trial

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ABSTRACT

Objective To examine the effectiveness of pH analysis of fetal scalp blood compared with lactate analysis in identifying hypoxia in labour to prevent acidaemia at birth.

Design Randomised controlled multicentre trial.

Setting Labour wards.

Participants Women with a singleton pregnancy, cephalic presentation, gestational age ≥ 34 weeks, and clinical indication for fetal scalp blood sampling.

Interventions Standard pH analysis (n=1496) or lactate analysis (n=1496) with an electrochemical microvolume (5 μ l) test strip device. The cut-off levels for intervention were pH < 7.21 and lactate > 4.8 mmol/l, respectively.

Main outcome measure Metabolic acidaemia (pH < 7.05 and base deficit > 12 mmol/l) or pH < 7.00 in cord artery blood.

Results Metabolic acidaemia occurred in 3.2% in the lactate group and in 3.6% in the pH group (relative risk 0.91, 95% confidence interval 0.61 to 1.36). pH < 7.00 occurred in 1.5% in the lactate group and in 1.8% in the pH group (0.84, 0.47 to 1.50). There was no significant difference in Apgar scores < 7 at 5 minutes (1.15, 0.76 to 1.75) or operative deliveries for fetal distress (1.02, 0.93 to 1.11).

Conclusion There were no significant differences in rate of acidaemia at birth after use of lactate analysis or pH analysis of fetal scalp blood samples to determine hypoxia during labour.

Trial registry ISRCT No 1606064.

INTRODUCTION

Fetal surveillance during labour often entails monitoring the fetal heart rate with a cardiotocograph. Normal results indicate that the fetus is getting enough oxygen.¹ In nearly half of all tracings, however, the results are not reassuring,² but only a small proportion of these fetuses are actually hypoxic. In such cases a diagnostic test is needed.

In 1962 Saling introduced sampling of blood from the fetus's scalp during labour to analyse pH as an indicator of hypoxia.³ This technique has since been

regarded as the ideal method of identifying intrapartum fetal hypoxia. Arbitrarily, a pH < 7.20 was chosen as cut-off value to recommend intervention. The analysis of pH is complicated, however, and needs a relatively large amount of blood (30–50 μ l), and sampling failure rates of 11–20% have been reported.^{4,5} It also does not discriminate between respiratory and metabolic acidaemia, the latter being associated with neonatal morbidity.^{6–8}

Lactate is a metabolite in anaerobic metabolism and reflects tissue hypoxia. Determination of lactate in blood from the fetus's scalp during labour has been studied since the 1970s.^{9–13} These observational studies have shown that lactate analysis has similar or better predictive properties compared with pH analysis in the identification of short term neonatal morbidity. It has been an option in clinical practice since a reliable electrochemical microvolume method became available, which needs only 5 μ l of blood.¹⁴ A randomised controlled trial comparing analyses of pH and lactate in fetal scalp blood showed significantly fewer failures in sampling with lactate analysis (odds ratio 16.1, 95% confidence interval 5.8 to 44.7) and no differences in short term neonatal outcome.⁴ The limited size of the study (341 cases), however, meant it could not compare metabolic acidaemia at birth or hypoxic ischaemic encephalopathy.¹⁵

We compared pH and lactate analyses of fetal scalp blood in the clinical management of intrapartum fetal distress to prevent severe acidaemia at birth.

METHODS

Participants

Ten labour ward departments in Sweden participated in this study. The first department was enrolled in the trial in December 2002 and during the autumn of 2003 additional departments entered the trial. The study closed at the same time for all departments (31 December 2005). Table 1 shows background data for

the participating units and the numbers recruited to the trial during the study period.

Recruitment and consent

The antenatal clinics gave information about the study to women in late pregnancy and requested consent at this time or when the woman was admitted in labour. If consent was not given, or if the woman was too distressed to be asked for consent, she was managed according to the standard protocols of the departments. Inclusion criteria for the trial were: singleton pregnancy, cephalic presentation, gestational age ≥ 34 weeks, and a non-reassuring fetal heart rate trace that the clinician in charge considered an indication for sampling fetal scalp blood. In total 3007 women were randomised. Fifteen were excluded because of multiple pregnancies or gestational age < 34 weeks, leaving 2992 for analysis (fig 1). Table 2 shows some descriptive data for the participating women in each group. We could not record the number of eligible women who were not included in the trial.

Randomisation and stratification

We used an internet based system for randomisation and data entry (www.medsclinet.se/laktat, MedSciNet AB, Stockholm, Sweden). When the clinician decided to sample fetal scalp blood, the woman was randomised to either pH or lactate analysis. If sampling or analysis failed, management was carried out on the basis of other clinical information. No change to randomised analysis was allowed, and if crossover occurred it was regarded as protocol violation. To adjust for differences in management routines or selection of patients, randomisation with stratification for the number of patients within each department was applied through the computer program. As some of the departments used fetal electrocardiography (the STAN monitor) as an adjunct to cardiotocography, we also stratified for the use of this method.

End points

Primary end points were metabolic acidemia in cord artery blood at birth (pH < 7.05 and base deficit > 12 mmol/l) and pH < 7.00 , both of which are

Fig 1 Recruitment, randomisation, and exclusions in trial

associated with neonatal morbidity.⁶⁻⁸ Base deficit was calculated for the blood compartment with the algorithm used by Radiometer blood gas analysers, recently reported to show a higher association with neonatal depression than base deficit calculated for the extracellular fluid compartment.¹⁶ As haemoglobin concentration in cord blood was not registered, we used the general approximation of a haemoglobin concentration of 150 g/l. Secondary end points were operative interventions (caesarean, ventouse, and forceps deliveries), Apgar scores < 7 at five minutes, and admissions to neonatal intensive care units.

Biochemical analyses and clinical guidelines

Lactate was measured with a commercially available microvolume test strip device (Lactate Pro, Arkray, Kyoto, Japan), a method that has previously been evaluated in intrapartum fetal monitoring (fig 2).^{12-14 17} As many different blood gas analysers were used, a commercial company (Equalis AB, Uppsala, Sweden) performed regular quality checks of the acid-base measurements. Each month we sent all departments water soluble standard solutions for analysis and compared results between the different analysers. The microvolume test device was also tested for lactate content in the solutions. These data will be presented elsewhere.

Guidelines for interpretation of the blood analyses were as follows: pH > 7.25 normal, 7.21-7.25 pre-acidaemia, < 7.21 acidaemia. Corresponding values for lactate were < 4.2 mmol/l normal, 4.2-4.8 mmol/l pre-acidaemia, > 4.8 mmol/l acidaemia, as recommended by Kruger et al.¹³ In cases of pre-acidaemia, we recommended repeat sampling of fetal scalp blood within 20-30 minutes if no other indication for intervention was present. The attending clinician decided on delivery in fetuses with acidaemia.

Statistical analyses

We calculated the sample size to detect a 100% increase in metabolic acidemia in cord artery blood at birth (primary outcome) in the lactate arm, from an estimated prevalence of 1.6% in the pH arm. We needed 2872 participants (1436 in each arm) to detect this difference with 80% power at 5% significance level,

Table 1 Data from participating departments during their study periods. Figures are numbers (percentages) of women

Hospital	No of deliveries	Caesarean section	Forceps/ventouse	Recruited*
1	10 861	2565 (23.6)	900 (8.3)	220 (2.0)
2	2 245	355 (15.8)	249 (11.1)	26 (1.2)
3	6 464	957 (14.8)	446 (6.9)	77 (1.2)
4	11 463	2868 (25.0)	1094 (9.5)	1152 (10.0)
5	8 341	1443 (17.3)	545 (6.5)	65 (0.8)
6	16 040	3757 (23.4)	1552 (9.7)	524 (3.3)
7	5 595	760 (13.6)	394 (7.0)	130 (2.3)
8	5 257	818 (15.6)	520 (9.9)	54 (1.0)
9	20 386	3078 (15.1)	1121 (5.5)	758 (3.7)
10†	—	—	—	1
Total	86 652	16 601 (19.2)	6821 (7.9)	3007 (3.4)

*Percentage of recruited patients in each department out of total number of deliveries.

†This department recruited only one patient so background data is not shown.

Table 2 | Descriptive data of groups according to method of monitoring for hypoxia. Figures are means (ranges) unless stated otherwise

	pH (n=1496)	Lactate (n=1496)
Maternal age (years)	33.0 (19-49)	32.5 (19-48)
Parity (%):		
Primiparous	1179 (78.8)	1155 (77.2)
Multiparous	317 (21.2)	341 (22.8)
Gestational age (weeks+days)	40+2 (34+0-44+2)	40+3 (34+0-43+6)
Fetal weight (g)	3575 (1590-5680)	3566 (1860-6110)
No with fetal weight <2500 g	39	36
Use of STAN-monitor (%)	393 (26.2)	392 (26.2)

two tailed. To show a 50% reduction, from 1.6% to 0.8%, we needed 2907 cases in each arm. Regarding pH <7.00 as end point and with an estimated prevalence of 4%, we needed to include 1141 cases in each arm to detect a 50% decrease or increase (to 2% and 6%, respectively). An independent steering committee conducted interim analyses after 1400 and 2400 randomised cases. After the second analysis (in November 2005) the committee recommended that we close the study after 3000 cases, estimated to be by the end of the year.

We analysed data according to “intention to treat” and have presented results as numbers, percentages, means, and ranges. We used χ^2 tests and relative risks with 95% confidence intervals to compare the pH and lactate groups. A P value <0.05 was considered significant. Analyses were performed in SPSS 15.0 (SPSS, Chicago, IL) and Statistica for Windows, version 7.0 (StatSoft, Tulsa, OK).

RESULTS

Of the 2992 included women, equal numbers were randomised to management by scalp blood pH and lactate determinations. Table 3 displays outcomes in

the randomised groups by intention to treat. There were no significant differences between the two groups in metabolic acidaemia (pH 3.6% *v* lactate 3.2%; relative risk 0.91, 95% confidence interval 0.61 to 1.36; difference -0.3 percentage points, -1.6 to 1.0 percentage points) or pH <7.00 (pH 1.8% *v* lactate 1.5%; 0.84, 0.47 to 1.50; difference -0.3 percentage points, -0.9 to 0.3 percentage points) in cord artery blood at birth. Operative interventions and the indication of fetal distress were also similar in the study groups. There were few cases with hypoxic ischaemic encephalopathy, and these were evenly distributed: six cases in each monitoring group. Three neonates died within the first week of life, two from lung hypoplasia as a consequence of diaphragmatic hernia and one from congenital cardiac fibrosis. All three were in the pH group, and none had acidaemia at birth.

The number of missing samples for measuring cord artery blood pH or full acid-base balance was higher in the pH group (174 and 181, respectively) than in the lactate group (120 and 136, respectively) (table 3). Among these cases, the rates of Apgar scores <7 at five minutes, operative interventions, and admissions to neonatal intensive care units were similar to the rates in the whole trial (data available from authors).

Scalp blood was sampled from one to nine times in each fetus. In the pH group, successful sampling or analysis was performed in 1008 fetuses with a total of 1628 analyses of pH. Corresponding figures in the lactate group were 1355 and 2301. For all pH analyses the mean value was 7.29 (SD 0.08, range 6.88-7.54). Mean lactate concentration in scalp blood was 3.5 (SD 1.8) mmol/l (range 0.8-15.9 mmol/l). Table 4 shows primary and secondary outcomes in relation to scalp blood pH or lactate values (normal, pre-acidaemia, or acidaemia) in cases where fetal scalp blood was collected within 60 minutes of delivery. Similar

Table 3 | Obstetric and neonatal outcome in groups according to method of monitoring for hypoxia analysed according to intention to treat. Figures are numbers (percentages)

	pH (n=1496)	Lactate (n=1496)	Relative risk for lactate <i>v</i> pH (95% CI)	P value
Metabolic acidaemia*	47 (3.6)	44 (3.2)	0.91 (0.61 to 1.36)	0.63
pH <7.00†	24 (1.8)	21 (1.5)	0.84 (0.47 to 1.50)	0.56
pH <7.10†	131 (9.9)	121 (8.8)	0.89 (0.70 to 1.12)	0.32
Caesarean section	415 (27.7)	452 (30.2)	1.09 (0.97 to 1.22)	0.14
Forceps/ventouse‡	416 (38.5)	370 (35.4)	0.92 (0.82 to 1.03)	0.15
ODFD	571 (38.2)	580 (38.8)	1.02 (0.93 to 1.11)	0.77
Apgar <7 at 5 min	40 (2.7)	46 (3.1)	1.15 (0.76 to 1.75)	0.51
NICU admission	164 (11.0)	167 (11.2)	1.02 (0.83 to 1.25)	0.86
Hypoxic ischaemic encephalopathy:				
Mild	4	5	—	—
Moderate	2	1	—	—
Severe	0	0	—	—
Perinatal mortality	3	0	—	—

NICU=neonatal intensive care unit; ODFD=operative delivery because of fetal distress.

*pH <7.05+base deficit >12 mmol/l. Samples for measuring cord artery acid-base balance missing in 181 in pH group and 136 in lactate group.

†Samples for measuring pH missing in 174 in pH group and 120 in lactate group.

‡Percentage calculated in vaginal deliveries.

Fig 2 | An electrochemical test strip meter needs only 5 µl of blood for lactate analysis

distributions in outcome were found when we analysed outcome with regard to sampling carried out within 30 minutes of delivery (data available from authors).

Protocol violation, when the patient was randomised to management by one of the methods but the clinician changed to the alternative method, occurred six times more often in the pH group than in the lactate group. Table 5 shows the specific reasons for not following the protocol. After randomisation failure to collect fetal scalp blood occurred less often in the lactate group compared with the pH group, but the difference was not significant (table 5).

We carried out a subanalysis of outcome according to use of ST analysis of the fetal electrocardiogram as an adjunct to cardiotocography. In this subgroup metabolic acidaemia occurred in 4.9% (18/371) in the pH analysis group and 2.7% (10/365) in the lactate management group (0.57, 0.26 to 1.21; $P=0.13$). Corresponding values in the cardiotocography only group were 3.1% (29/944) and 3.4% (34/995) (1.11, 0.68 to 1.81; $P=0.67$). In the ST analysis subgroup 3.0% (11/372) in the pH management group had a pH <7.00 compared with 1.9% (7/368) in the lactate management

group (0.64, 0.25 to 1.64; $P=0.35$). Corresponding values in the cardiotocography only group were 1.4% (13/950) and 1.4% (14/1008), respectively (1.02, 0.48 to 2.15; $P=1.00$).

DISCUSSION

This large randomised trial of the effectiveness of pH and lactate analyses in fetal scalp blood in the clinical management of intrapartum fetal distress and prevention of acidaemia at birth found no significant difference in the rate of metabolic acidaemia with either method. The risk difference of −0.3 percentage points and the confidence interval for the difference (−1.6 to 1.0 percentage points) indicate that there is no clinically significant difference either. Blood sampling and assessments were more successful for lactate than for pH, mainly because of the smaller amount of blood needed for lactate analysis.

Failure of sampling and analysis

The higher failure rate with pH determination was significant and led to protocol violations on 155 (10.4%) occasions in this group—that is, the clinician decided to do a lactate analysis when pH blood sampling or analysis failed—compared with 18 cases (1.2%) in the lactate group. We did not specifically measure the rate of sampling failure, but apart from the 10.4% recorded (failures that led to protocol violation), a number of failures are likely among those where fetal scalp blood was not collected and no reason was given. These findings are in accordance with previous publications, which have reported failure rates with pH blood sampling or analysis in 11–21%.^{4,5} Our failure rate with lactate analyses (1.2%) was similar to that previously reported (1.7%).⁴ Tuffnell et al reported that in 35% of cases it took more than 20 minutes from the decision to sample fetal scalp blood until the result of the analysis was available and in 9% it took over 30 minutes.⁵ This risk factor can lead to unforeseen delay in management, in view of recommendations that sampling fetal scalp blood is repeated within 20–30 minutes in fetuses with pre-acidaemia.³ Both sampling and analysis are much quicker with lactate analysis,⁴ thus minimising the risk of delay in clinical management. Therefore, it is more attractive to use in the clinical setting, both for the women in labour (short blood sampling time) and for the clinician.

Table 4 | Primary and secondary outcomes in relation to scalp blood values (normal, pre-acidaemia or acidaemia¹³). Figures are fetuses in whom fetal scalp blood was collected within 60 minutes of delivery (percentage of cases in each group)

	Fetal scalp blood pH (n=508)			Fetal scalp blood lactate (n=684)		
	>7.25 (n=281)	7.25–7.21 (n=92)	<7.21 (n=135)	<4.2 (n=344)	4.2–4.8 (n=73)	>4.8 (n=267)
Metabolic acidaemia	7 (2.5)	3 (3.3)	10 (7.4)	6 (1.7)	0	19 (7.1)
pH <7.00	4 (1.4)	2 (2.2)	5 (3.7)	0	0	10 (3.7)
Apgar <7 at 5 minutes	9 (3.2)	2 (2.2)	10 (7.4)	4 (1.2)	1 (1.4)	23 (8.6)
ODFD	81 (28.8)	58 (63.0)	118 (87.4)	79 (23.0)	50 (68.5)	251 (94.0)

ODFD=operative delivery because of fetal distress.

Neonatal outcome

We found no significant differences in the rates of acidaemia at birth between the study arms or any differences in the rates of low Apgar scores at five minutes or admissions to neonatal intensive care units. The relative risk for metabolic acidaemia in the lactate analysis arm was 0.91 (95% confidence interval 0.61 to 1.36) compared with the pH analysis.

Our findings agree with those of a previous randomised controlled trial, which was designed mainly as a feasibility study.⁴ In that study, however, the number of cases included (n=341) did not allow comparison of significant neonatal outcome. Although we used the same device for lactate analysis, they used a lower lactate cut-off value to define acidaemia (4.2 mmol/l v 4.8 mmol/l).

Severe neonatal outcome from intrapartum asphyxia is rare. Hypoxic ischaemic encephalopathy should ideally be a primary end point. In this large study, however, in which we included only high risk cases with non-reassuring or ominous traces on cardiotocography, the prevalence of hypoxic ischaemic encephalopathy was 4/1000. This made it impossible for us to use it as an end point to be able to show significant differences. Our primary end points—metabolic acidaemia and pH <7.00—were also rare, with a prevalence of between 3.6% and 1.5%. The low prevalence of acidaemia at birth in Western populations made calculations of sample size realistic only for showing large differences in outcome (50–100%). This is also why the confidence intervals are wide. As the actual rate of metabolic acidaemia in the pH arm was higher than initially estimated, however, the study had the power to evaluate smaller differences between the study arms than initially expected.

Operative interventions

As expected (because of how we derived cut-off values for recommended interventions) operative interventions in terms of instrumental vaginal or caesarean deliveries were evenly distributed. In a population in which fetal scalp blood sampling was carried out, Kruger and

coworkers¹³ found that the 25th centile for pH was 7.21, which is close to the suggested cut-off value of 7.20.³ Correspondingly, the 75th centile for lactate was 4.8 mmol/l, a concentration shown to be below the optimum cut-off value to predict severe neonatal outcome.¹³ This implies that about one out of four samplings should have an abnormal result, regardless of whether pH or lactate is analysed. If a high rate of “crossovers” had not occurred in the pH group—that is, if lactate had not been analysed instead of pH in cases with failed pH sampling or analysis—we might have expected a higher intervention rate in the pH group indicated by worrying fetal heart rate traces.

Fetal scalp blood sampling has not been used in the United States for many years.¹⁸ Availability of a simple bedside method might reintroduce it into clinical practice and could help to reduce their high rate of caesarean section.

Fetal scalp blood acidaemia

With the simplified technique of lactate analyses we had around 40% more lactate analyses than pH analyses to evaluate. Scalp blood analysis also identified a higher proportion of abnormal results—that is, acidaemia—in the lactate arm than in the pH arm. The proportion of neonates with acidaemia at birth was slightly lower when we used lactate analyses, a difference that was not significant. The only significant difference between the study arms regarding outcome of cases with scalp blood acidaemia or pre-acidaemia was an increased proportion of operative delivery indicated by acidaemia or pre-acidaemia in the lactate group. Clinicians involved in the trial claimed that previous experience with pH analysis made them more confident in managing timing for intervention with this method compared with the new lactate device.

Sampling fetal scalp blood is a diagnostic test in cases with suspicious or worrying results on cardiotocography. When one test has yielded alarming results, it is extremely important that an additional test has a low frequency of “false negatives.” In this study six babies had pH <7.00 and 10 had metabolic

Table 5 | Reasons for protocol violation or not collecting fetal scalp blood and their distributions between two groups according to method of monitoring for hypoxia

	pH	Lactate	Relative risk for lactate v pH (95% CI)	P value
Protocol violation:				
Total	164 (11.0)	22 (1.5)	0.13 (0.09 to 0.21)	<0.001
Failed blood sampling	146	18	—	—
Failed analysis	9	0	—	—
Double sampling (pH+lactate)	9	4	—	—
No fetal scalp blood collected:				
Total	106 (7.1)	81 (5.4)	0.76 (0.58 to 1.01)	0.06
Rapid delivery	8	21	—	—
Expedite delivery	5	5	—	—
Reassuring CTG	7	4	—	—
Withdrew consent	1	3	—	—
No reason given	85	48	—	—

CTG=cardiotocogram.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Fetal scalp blood can be tested for hypoxia in fetuses with worrying intrapartum heart rate traces

pH analysis has a sampling or analysis failure rate of 11–20% and has been excluded from clinical practice in the US

WHAT THIS STUDY ADDS

There was no difference between assessment of fetal acidemia with lactate analysis or pH analysis

At worst, replacement of pH measurement with lactate measurement could result in a one third increase in acidemia at delivery

acidemia at birth when fetal scalp blood pH was >7.20 determined within 60 minutes of delivery. Corresponding figures for cases with scalp blood lactate <4.8 mmol/l were none with pH <7.00 and six with metabolic acidemia. These results suggest that the lactate method is reliable from this perspective.

It is difficult to draw any firm conclusions from outcome in cases with scalp blood acidemia. Firstly, all fetuses with scalp blood acidemia should be delivered immediately, according to clinical guidelines, to minimise fetal compromise. Secondly, we need a cut-off value for the test that suggests intervention before severe acidemia is established—that is, preventive intervention. Quick management is needed when a woman is admitted to a labour ward with signs of possible fetal distress, and in these cases lactate analysis might be useful. In such cases timing does not allow preventive action if acidemia is already established. Contrarily, it is vital that fetal distress during labour is detected at an early stage, before the fetal acid-base balance is severely compromised. Future research will show if the present cut-off value, 4.8 mmol/l, is the optimal level and if trends from repetitive measurements will add useful information from this perspective.

Single or combined analyses

The combined measurement of pH and lactate is no better at predicting abnormal outcome than each method individually.^{12 13} It might only increase the number of abnormal results and thereby the rate of operative intervention. If combined analyses are carried out, however, a high lactate value indicates action, even if the pH is normal. Severely depressed newborns have been reported with this combination of findings.¹³

Weakness of the trial

A potential cause of bias was that larger numbers of values for cord artery acid-base balance were missing in the pH group, which theoretically could have concealed cases with acidemia at birth. The higher number of missing values in this group might be explained if the clinicians involved forgot to register acid-base values at birth when fetal scalp blood

sampling had failed and this occurred more often in the pH group. Whether the performance of lactate determinations could be improved by analysing trends with repeat fetal scalp blood sampling or by choosing another cut-off value could be evaluated in future research.

Conclusions

We found that lactate analysis and pH analysis of fetal scalp blood had comparable results in the management of intrapartum fetal distress. We found no significant differences in birth acidemia, operative interventions, low Apgar scores at five minutes, or admissions to neonatal intensive care units. Sampling failure was more common in the pH group. One might therefore expect higher operative intervention rates with pH analysis if the alternative method is not available. Combined analyses are not recommended as they are likely to increase the number of interventions without decreasing metabolic acidemia at birth.

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Contributors: LN had the original idea for the study, launched the network of collaborators, contributed to study design, the creation of a web based randomisation and reporting database, analysis and interpretation of data, and writing the paper and is guarantor. EW-I contributed to the study design, implemented the guidelines to all departments, contributed to analysis and interpretation of the data and writing the paper. CL, MN, AHe, DP, AHa, A-LB, MC, MS, and U-BW contributed to the study design, analysis and interpretation of data, and writing the paper. All authors have seen and approved the final version.

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Competing interests: EW-I and LN are shareholders in Obstecare, a company dealing with development of IT based decision support for labour dystocia. No product is yet on the market.

Ethical approval: Karolinska Institutet, Stockholm, Sweden (file record 109/02).

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