

Included articles

STAN, HTA-report 2011:3

Author, year	Study design, number of patients, withdrawals/drop-outs	Results Intervention and control group	Comments	Quality of study
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FD=fetal distress EDA=epidural analgesia FBS=Fetal Blood Sampling CS=Cesarian Section VO=Vacuum outlet				
<p>Amer-Wahlin, I, Hellsten, C et al. (2001). "Cardiotocography only versus cardiotocography plus ST analysis of fetal electrocardiogram for intrapartum fetal monitoring: a Swedish randomised controlled trial." <i>Lancet</i> 358(9281): 534-538.</p>	<p>RCT 3 center 4966 included (2519 STAN, 2447 CTG).</p> <p>Missing data on primary outcome in 14.7% Protocol violations detected during interim analysis. Subgroup analysis after exclusion of 574 (11.6 %) with inadequate recordings and 8 with malformations(?). These results are not considered.</p>	<p>Metab.acidosis ecf CTG 31/2079 and STAN15/2159 RR 0.47(0.25-0.86), p= 0.02</p> <p>Correction feb.2011 CTG 24/2079 and STAN12/2159 RR 0.49 (0.24-0.97)p=0.04 error in data collection (pers com. PI Marsal).</p> <p>Fewer op.deliveries for FD w STAN RR 0.83 (0.69-0.99) p= 0.047</p> <p>NS difference for CS or VO separately or for other indications. No diff. in neonatal outcome</p> <p>Misprint in Tab.3 and abstract: Met acidosis 2% (CTG) should be 1.5%.</p>	<p>EDA sign. more common in CTG group(p=0.03) Age and parity distribution of EDA-pts would have been useful</p> <p>Faults and misclassifications in results investigated by the University of Lund and The Swedish Research Council. See ref. Corrected data via pers comm. Definitive corrections pending.</p>	Low
<p>Ojala, K et al. (2006). "A comparison of intrapartum automated fetal electrocardiography and conventional cardiotocography--a randomised controlled study." <i>BJOG</i>; 113: 419-23</p>	<p>RCT Tertiary hospital 1483 pts 11 excluded 733 STAN + 739 CTG=1472 Missing data from primary outcome in 2.6% and 2.3% Met acidosis prim outcome 714+722=1436 patients analyzed Both external and internal CTG used in CTG-group. Clear flow chart</p>	<p>Metabolic acidosis blood RR 2.43 (0.86-6.85), p=0.093</p> <p>Op deliveries FD CS RR 1.01(0.50-2.05) p=0.262 VO RR 0.76(0.50-1.15 p= 0.206 All indications: CS RR 1.35(0.86-2.07) p=0.124 VO RR 0.89 (0.66-1.21) p=0.530</p> <p>FBS RR 0.45 (0.33-0.61) p<0.001-favour STAN</p>	<p>Power for met.acidosis not enough. Well performed and clearly reported study</p>	Medium
<p>Vayssière, C et al. (2007). "A French randomized controlled trial of ST-segment analysis in a population with abnormal cardiotocograms during labor." <i>Am J Obstet Gynecol</i> 197: 299. e1-299.e6.</p>	<p>RCT 799 pts 399 STAN and 400 CTG = 799 Risk population Primary outcome operative deliveries</p>	<p>Op deliveries FD RR 0.91 (0.75-1.10) All indications RR 0.98 (0.86-1.11) Fewer individuals for FBS with STAN RR 0.44 (0.36-0.52) Met acidosis 8 cases in STAN and 5 in CTG group, ns</p>	<p>Power for met.acidosis not enough</p> <p>Bayesian model calculations confirmed a lack of effect</p>	Medium

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<p>Westerhuis, ME et al. (2010). "Cardiotocography plus ST analysis of fetal electrocardiogram compared with cardiotocography only for intrapartum monitoring: a randomized controlled trial." <u>Obstet Gynecol</u> 115: 1173-1180.</p> <p>Westerhuis, ME et al. (2011) <u>Obstet Gynecol.</u> vol 117 Letter to the editor p. 406-7. Correction p.412</p>	<p>RCT No of pts 5681 14 excluded STAN 2827 CTG 2840 Riskpatients Primary outcome met acidosis Intention to treat analysis Clear flow chart</p>	<p>Met. acidosis ecf NS 20/2827 resp 30/ 2840 RR 0.70 (0.38-1.28) NNT 252. Correction 2011 19/ 2827 resp 27/2840, p=0.70 (0.38-1.28) blood 45/2827 and 74/2840 RR 0.63 (0.42-0.94) Correction 2011 41/2827 AND 66/2840 RR 0.63 (0.42-0.94) favour STAN</p> <p>Need for FBS less with STAN RR 0.52 (0.46-0.59).</p>	<p>A well performed and replicable study</p>	<p>Medium</p>
<p>Noren, H, Blad, S et al. (2006). "STAN in clinical practice--the outcome of 2 years of regular use in the city of Gothenburg." <u>Am J Obstet Gynecol</u> 195:7-15</p>	<p>Prospective observational study Development over two years with STAN 4830/14687 deliveries (Sahlgrenska-Ö & Mölndal) No inferior registrations noted Outcomes: Met.acidosis, neonatal outcome, op deliveries Wider inclusion criteria second year Mostly risk pts but also normal for training. 8 breech presentations</p>	<p>Met. acidosis decreased from 0,76% till 0,44% with increased STAN-use (p=<0,05). Neonatal hypoxic encefalopati had low frequency 0,55 and 0,68 per 1000 deliveries No of op deliveries the same.</p>	<p>STAN-use increased from 28,1% till 37,7% during the period.</p> <p>Umbilical cord sampling from 90 % both years.</p> <p>Groups not comparable. More risk pts in STAN-group</p>	<p>Medium</p>
<p>Melin, M et al. (2008). "Changes in the ST-interval segment of the fetal electrocardiogram in relation to acid-base status at birth." <u>BJOG</u> 115: 1669-1675.</p>	<p>Case-control study Lund univ. hosp. 2002-2007</p> <p>Neonates with acidemi 1) Severe met. 24 2) Moderat met. 48 3) Acidemi 52 4) Preacidemi 265 st Controls 117 randomly selected controls</p> <p>Retrospectiv analysis of CTG+ST Inclusions if a STAN baseline was registered for more than 60 min and if data from the last 20 min before delivery were available.</p>	<p>2/3 of severe and less than half of the with moderate acidemi had ST- events coinciding with CTG changes. Intervention was recommended according to guidelines in 96%, 62%, 73% and 49% of resp cases and in 23 % among controls. Shows lack of specificity for CTG but also a higher sensitivity than with STAN events</p>		<p>High</p>

Excluded articles

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Reference	Study design	Reason for exclusion
Westgate, J., M. Harris, et al. (1992). "Randomised trial of cardiotocography alone or with ST waveform analysis for intrapartum monitoring." <u>Lancet</u> 340 (8813): 194-198.	Interim analysis	Not computerized
Westgate, J., M. Harris, et al. (1993). "Plymouth randomized trial of cardiotocogram only versus ST waveform plus cardiotocogram for intrapartum monitoring in 2400 cases." <u>Am J Obstet Gynecol</u> 169 (5): 1151-1160.		Not computerized
Finnish Office for Health Care Technology ,(2007). STAN follow up during labor Helsinki: Finnish Office for Health Care Techn. Assessment (FinOHTA)		Not identified
Amer-Wahlin I, Bordahl P, et al. (2002). "ST- analysis of the fetal electrocardiogram during labor: Nordic observational multicenter study." <u>J Matern Fetal Neonatal Med</u> 12 : 260-266	Retrospective multicenter study. Study of prototype for protocol evaluation	Study basis for protocol that is evaluated in other studies No action on STAN events
Dervaitis K, et al. (2004). "ST segment analysis of the fetal electrocardiogram plus electronic fetal heart rate monitoring in labor and its relationship to umbilical cord arterial blood gases." <u>Am J of Obstet Gynecol</u> 191 : 879-84	Prospective cohort study from Canada with retrospective analysis of STAN®.	No control group Not within PICO
Devoe LD, et al. (2006). United States multicenter clinical usage study of the STAN 21 electronic fetal monitoring system. <u>Am J Obstet Gynecol.</u> 195 :729-34.	Demonstrates compliance with protocol	Uses american routines for interpretation
Doret M, et al. (2011). Use of peripartum ST analysis of fetal electrocardiogram without blood sampling: A large prospective cohort study. <u>Eur J Obstet Gynecol Reprod Biol.</u> doi:10.1016/j.ejogrb.2010.12.042.	Observational study. No comparison	Low pH but high Apgar Not within PICO
Doria V, et al. (2007). "Review of the first 1502 cases of ECG-ST waveform analysis during labour in a teaching hospital." <u>BJOG</u> 114 : 1202-1207.	Prospective observational Tertiary centre in London High Risk pts Non adherence to guidelines	Not within PICO
Kale A, et al. (2008). "Effect of availability of fetal ECG monitoring on operative deliveries." <u>Acta Obstet Gynecol Scand</u> 87 : 1189-1193.	Observational study Historical controls	No of operative deliveries for FD decreases but total number equal. High frequency of acute CS. Unclear what role STAN® had. Low quality
Kwee A, et al. (2004). "STAN S21 fetal heart monitor for fetal surveillance during labor: an observational study in 637 patients." <u>J Matern Fetal Neonatal Med</u> 15 : 400-407.	Prosp. Obs. Study 637 patients STAN at dr's discretion Drop outs (29.5%) as controls	Groups not comparable Selection bias Low quality
Luttkus A, et al. (2004). "Fetal scalp pH and ST analysis of the fetal ECG as an adjunct to CTG. A multi-center, observational study." <u>J Perinat Med</u> 32 : 486-494.	Multicenter obs study 6999 pts from 10 centra in Europe Tot. no of deliveries unknown STAN and FBS at dr's discretion. Selection bias.	FBS and umbilical cord results together. Comparison of two diagnostic tests. Low quality

Reference	Study design	Reason for exclusion
Amer-Wahlin I, Ingemarsson I, et al. (2005). "Fetal heart rate patterns and ECG ST segment changes preceding metabolic acidaemia at birth." <i>BJOG</i> 112 : 160-165.	Case-control Interpretation evaluation	Not according to PICO
Heintz E, et al. (2008). "The long-term cost-effectiveness of fetal monitoring during labour: a comparison of cardiotocography complemented with ST analysis versus cardiotocography alone." <i>BJOG</i> 115 : 1676-1687.	Health economy	Not in PICO Uses old technology
Massoud M, et al. (2007). "Fetal electrocardiotocography in labor and neonatal outcome: an observational study in 1889 patients in the French center of Edouard Herriot, Lyon." <i>J Matern Fetal Neonatal Med</i> 20 : 819-824.	Tertiary center. Compared 2 periods with STAN	Not within PICO.
Luzietti R, et al. (1999). "European Community multi-Center Trial "Fetal ECG Analysis During Labor": ST plus CTG analysis." <i>J Perinat Med</i> 27 : 431-440.		Old technology Not within PICO
Noren, H., I. Amer-Wåhlin, et al. (2003). "Fetal electrocardiography in labor and neonatal outcome: data from the Swedish randomized controlled trial on intrapartum fetal monitoring." <i>Am J Obstet Gynecol</i> 188 : 183-192.	Case –control study 4966 term children Incl criteria: 351 to NICU Retrospective analysis Outcome: perinatal death, neonatal encefalopatý, metabolic acidosis	Numbers not congruent with original study. Other reasons than acidosis behind encephalopathy
Noren H, Luttkus A, et al. (2007). "Fetal scalp pH and ST analysis of the fetal ECG as an adjunct to cardiotocography to predict fetal acidosis in labor--a multi-center, case controlled study." <i>J Perinat Med</i> 35 : 408-414	Case-control study	Does not measure metabolic acidosis but a mixture with respiratory.
Palmgren Colov Nina (2007). Undervisningsbehov over tid ved implementering af en ny fosterovervågningsteknologi VIDENSKAB OG PRAKSIS sep 2007	Descriptive study of the introduction of STAN. No controls.	Not within PICO
Ross MG, et al. (2004). ST-segment analysis of the fetal electro cardiogram improves fetal heart rate tracing interpretation and clinical decision making <i>Fetal Neonatal Med.</i> 15 :181-5.	Decision making	Not within PICO
Rzepka R, et al. (2010). Clinical outcomes of high-risk labours monitored using fetal electrocardiography. <i>Ann Acad Med Singapore.</i> 39 :27-32.	Observational study	No controlgroup
Welin AK, et al. (2007). STAN, a clinical audit: the outcome of 2 years of regular use in the city of Varberg, Sweden <i>Acta Obstet Gynecol Scand.</i> 86 :827-32.	Retrospective study	Follow-up study to evaluate the introduction of STAN