Foetal monitoring during labour: practice versus theory in a region-wide analysis

Y. Jacquemyn¹, E. Martens², G. Martens²

¹Department of Obstetrics and Gynaecology, ²Center for Perinatal Epidemiology - SPE University Hospital Antwerp - UZA, Edegem (Belgium)

Summary

Purpose: To evaluate cardiotocography (CTG) alone versus CTG and ST-analysis (STAN) in daily obstetric practice in a complete region. *Methods:* Prospective registration in the region of Flanders in combination with standard registration of perinatal outcome. *Results:* Of 62,606 term deliveries registered, 57,141 (91.3%) were available for complete analysis. In 50,748 (88.8%) CTG alone and in 6,393 (11.6%) CTG + STAN was used. STAN was used significantly more in case of hypertension, diabetes and induction of labour and was associated both in univariate and multivariate analysis with significantly more secondary caesarean section for suspected foetal distress, instrumental vaginal delivery, low Apgar score and need for neonatal intensive care. There was no difference in perinatal death or asphyxia. *Conclusion:* ST-analysis versus CTG results in more caesarean sections, instrumental vaginal deliveries and neonatal intensive care. This can not be explained solely by its use in more complicated cases as in multivariate analysis including hypertension, diabetes and induction of labour ST analysis persists as a significant factor. We hypothesise that this could be explained by less well trained users not adhering to STAN-guidelines.

Key words: ST-analysis; Cardiotocography; Foetal monitoring; Labour.

Introduction

Since the year 2000 foetal monitoring with foetal STanalysis (STAN, Neoventa, Sweden) has been progressively introduced in Europe. From the start of this period, experiences from dedicated single hospitals [1, 2] confirming the results of the larger multicenter randomised trials [3], have been reported. Most users have quickly adopted this new technology, and in the daily practice of busy clinical wards, most users seem to feel confident with 'the new machine" [4, 5].

Less is known on what happens with the performance of foetal ST-analysis versus cardiotocography (CTG) alone when this technology is used outside randomised trials and outside dedicated centers, in large and small maternity wards with midwives and gynaecologists having less interest or a lower level of education in foetal electrocardiography and cardiotocography.

To evaluate the performance of CTG alone versus CTG + ST-analysis for foetal monitoring in term deliveries in general obstetric practice, we started a prospective registration of foetal monitoring in the region of Flanders, the northern half of Belgium.

Material and Methods

The Center for Perinatal Epidemiology routinely collects anonymised data on all deliveries in the region of Flanders and covers 100% of hospital deliveries (< 1% are home deliveries). From January 1 to December 31, 2009 a prospective registration was added to the routine file, asking for: "foetal monitoring: yes/no; if yes by: STAN, CTG alone, auscultation alone, foetal scalp blood sampling". For this analysis we included only deliveries from 37 weeks gestational age on (as STAN is not validated before this period); primary caesarean sections were excluded.

Other registered outcomes were: gestational age (in weeks), presence or absence of maternal hypertension (not further specified), diabetes (not further specified), induction of labour, secondary caesarean section, use of forceps or vacuum extractor, Apgar score after 1 and 5 min, need for neonatal reanimation, transfer to a neonatal unit or to the neonatal intensive care unit (NICU), birth weight (in grams), foetal mortality during labour and delivery, early (the first 7 days) and late (until 28 days) neonatal mortality, neonatal asphyxia (as diagnosed by the treating paediatricians).

Outcomes were compared in the two groups: CTG alone versus CTG + ST-analysis.

Statistical analysis was performed with SPSS 17.0. Dichotomous variables were compared using chi square testing and continuous variables with Student's t-test; significance was accepted at p < 0.05.

After univariate analysis, differences between groups were further evaluated using multiple logistic regression.

Results

In 2009 there were 68 maternity wards in the region of Flanders. Of these, 64 (94%) had at least one STANmachine available in 2009. In only one of these 68 maternity wards was foetal scalp blood sampling performed in 2009. The total number of deliveries in the region was 68,774 in 2009, of which 62,606 (91%) were at 37 or more weeks. Actually in the group < 37 weeks, 210 STAN-monitors had been applied, but these were not included in the rest of our analysis. In 5,465 (8.7%) data on the mode of foetal monitoring were missing, leaving 57,141 cases for complete evaluation. In 50,748 (88.8%) of these CTG alone was used and in 6,393 (11.2%) CTG and STAN. There were 512 (0.8%) foetal scalp blood samplings, but as these were all performed in a single

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hospital they were not further analysed in this regional study.

Table 1 gives an overview of the perinatal outcome in the CTG alone and in the CTG + STAN group.

STAN was significantly more used in pregnancies complicated by hypertension or diabetes and in case of induction of labour. In the STAN group more secondary caesarean sections were performed in general (19.5% vs 6.2%), but specifically caesarean section was more often performed for suspected foetal distress in the STAN group (8.4% of the total group, 43.3% of all caesarean sections) as compared to the CTG alone group (6.2% of the total group and only 19.8% of all caesarean sections). To discriminate whether the use of foetal ST-analysis was an independent factor determining this rising number of caesarean sections for foetal distress a multiple logistic regression was performed including hypertension, diabetes, induction of labour, maternal age (more or less than 35 years) having had a previous caesarean section, parity, birth weight > 4500 g or < 2500 g and the use of CTG alone or STAN + CTG.

Induction of labour, STAN, low birth weight (< 2500 g), maternal age (> 35 years), primiparity and having had a previous caesarean section were shown to be significant variables (all p < 0.001); hypertension (p = 0.24), diabetes (p = 0.07), and birth weight > 4500 g (p = 0.83) were not significant.

Instrumental vaginal delivery was also more frequent in the STAN + CTG group (19% vs 9.8%). Here we also performed a multiple logistic regression including hypertension, diabetes, induction of labour, maternal age (more or less than 35 years), having had a previous caesarean section, parity and the use of CTG alone or STAN + CTG. In this model diabetes (p = 0.03), birth weight < 2500 g (p = 0.01) induction of labour (p < 0.001), use of STAN (p < 0.001), birth weight > 4500 g (p < 0.001), maternal age > 35 years (p < 0.001), primiparity (p <0.001) and having undergone a previous caesarean section (p < 0.001) were significant variables.

There were significantly more babies born with a low Apgar scores both after 1 and 5 min in the CTG + STAN group, resulting in more cases of neonatal reanimation and more transfers to a neonatal intensive care unit. We performed a multiple regression analysis including as factors: maternal hypertension, diabetes, induction of labour, caesarean section, instrumental vaginal delivery, birth weight < 2500 g or > 4500 g and STAN + CTG versus CTG alone. The significant variables related to transport to a NICU were: diabetes (p = 0.001), induction of labour (p = 0.005), STAN (p < 0.001), birth by secondary caesarean section (p< 0.001) vaginal instrumental delivery (p < 0.001), birth weight > 4500 g (p < 0.01) and maternal age > 35 years (p = 0.004). A previous caesarean section (p = 0.91), parity (p = 0.15), hypertension (p = 0.89) and birth weight (p = 0.15)0.09) were not significant in the model.

No significant difference in intrapartum, and early or late neonatal death were noted. Asphyxia (as a clinical diagnosis by the treating paediatrician) was not different between the STAN and CTG alone group.

Table 1. — Data on term pregnancies in labour monitored with STAN + CTG versus CTG alone.

Total N = 57,141 STAN + CTGCTG alone ^b N = $6.393N = 50,748$							
	N = 0,59	% %	N N	%	Р	OR	95% CI
Hypertension	470	7.4	1997	3.9	< 0.001	1.75	1.61-1.91
Diabetes	172	2.7	1046	2.1	0.001	1.26	1.10-1.46
Induction	2534	39.6	12078	23.8	< 0.001	1.31	1.82-2.00
Caesarean section	1244	19.5	3159	6.2	< 0.001	2.89	2.74-3.05
Caesarean for							
foetal distress	539	8.4	627	1.2	< 0.001	4.42	4.13-4.72
Ventouse	1119	17.9	4693	9.2	< 0.001	1.87	1.77-1.99
Forceps	73	1.1	314	0.6	< 0.001	1.69	1.38-2.09
Apgar 1 < 7	689	10.7	2717	5.4	< 0.001	1.91	1.77-2.05
Apgar $5 < 7$	157	2.5	561	1.1	< 0.001	1.98	1.72-2.28
Reanimation	536	8.4	1944	3.8	< 0.001	2.02	1.86-2.18
Ν	967	15.1	4678	9.2	< 0.001	1.63	1.53-1.73
NICU	163	2.5	689	1.4	< 0.001	1.73	1.50-1.99
< 2500 g	177	2.8	1138	2.2	0.008	1.21	1.05-1.39
> 4500 g	71	1.1	610	1.2	0.52	0.93	0.74-1.16
Intrapartum death	2	0.03	11	0.02	0.63	1.37	0.38-4.92
Early neonatal							
death	3	0.05	19	0.04	0.71	1.22	0.43-3.49
Late neonatal							
death	10	0.15	34	0.07	0.01	2.03	1.18-3.51
Asphyxia	10	0.16	41	0.08	0.06	1.75	1.01-3.03
N: neonatal unit/NICU: Neonatal intensive care unit; OR: Odds ratio/IVH: intraventricular							

hemorrhage.

Discussion

It can be hypothesised that in real life, in less dedicated centers, guidelines concerning cardiotocography and foetal ST-analysis are not as thoroughly followed as in the setting of a randomised trial. Our study is not randomised, and it does not reflect the value of STAN + CTG versus CTG alone in comparable cases but does reflect the clinical scenario of daily practice using STAN and CTG.

STAN was clearly more used in high-risk deliveries including diabetes, hypertension, and in case of induction of labour. In the STAN group slightly more caesarean sections were performed, but if a caesarean is done, this is twice as often due to foetal distress. The same can be said for instrumental vaginal deliveries.

In contradiction to the results from randomised controlled trials showing less or the same frequency of interventions with no change in neonatal outcome [3, 7, 8] in this descriptive analysis, in a real life setting STAN results in more interventions. This difference can not be explained solely by the fact that STAN was more often used in high-risk situations such as hypertension, diabetes and induction of labour, because in multivariate analysis the use of STAN persisted as a significant factor in relation to instrumental delivery, cesarean section and need for neonatal intensive care.

In this region-wide study we have no data on metabolic acidosis as umbilical cord blood gas analysis is not generally performed. Only data on Apgar score and clinical diagnosis of asphyxia and transfer to a neonatal intensive care unit are available. Neither can we comment on changes in the method of foetal monitoring in Flanders as no previous data are available. Other studies have suggested a relation between a high rate of CTG and ST-analysis and reduction in cord blood acidosis rate [10]. In our study STAN was associated with lower Apgar scores and more transfers to a neonatal intensive care unit despite, or due to, more interventions (caesarean sections and instrumental vaginal deliveries).

As already mentioned in the multivariate analysis, part of this can be explained by the application of STAN in a selected group of high-risk patients (diabetes, hypertension and induction of labour), but even then the data strongly suggest that either the STAN methodology and guidelines are not correctly followed in clinical practice or the methodology fails in a large general obstetric population when performed by midwives and gynaecologists who are not specifically dedicated to foetal monitoring.

Although with experienced users a high level of interobserver agreement in clinical decision making for CTG + STAN as compared to CTG alone has been reported, nothing is known as to whether this high level of agreement is still present when working in day-to-day busy units with different midwives and doctors [11, 12].

Several authors have mentioned that less foetal blood sampling was necessary in the STAN versus the CTG alone group. We believe the practice of foetal blood sampling has become so rare, as demonstrated in our data, that for a large part of Europe this finding is of no practical value [6, 13].

Different reasons can be given for failure of STAN in daily practice including: lack of continuous training and a high incidence of false-positive ST-events resulting in failure to act when a significant ST-event occurs [14]. It has been demonstrated that outcomes equal to those of the randomised controlled trials can be achieved in busy non-academic district hospitals, but this means continuous evaluation and training which is far more difficult to reach in a complete region including small maternity wards [15]; most maternity units in Flanders have less then 1,000 deliveries a year. We can not exclude a selection in which STAN was used only in the "worst cases'.

All this resulted in a finding that is in contrast with all other published reports: in this region-wide survey the use of STAN versus CTG was associated with more intervention, a worse neonatal outcome and more asphyxia in term babies.

It cannot be completely excluded that this outcome is due to the technology itself, but it seems more convincing that our data stress the extreme importance of continuous training and evaluation of the users.

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Address reprint requests to: Y. JACQUEMYN, M.D. Obstetrics UZA Antwerp university Hospital Wilrijkstraat, 10 - 2650 Edegem (Belgium) e-mail: yves.jacquemyn@uza.be