Computerised cardiotocography in a high-risk unit in a developing country — its influence on inter-observer variation and duration of recording

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Objective. To determine the role of computer-assisted cardiotocography in an obstetric special care unit and its influence on inter-observer variation in interpretation, proposed management and monitoring time.

Design. A prospective comparative study.

Setting. The obstetric special care unit, Tygerberg Hospital, W. Cape.

Study population. A group of 10 registrars in obstetrics who have had experience in the interpretation of both standard and computer-assisted cardiotocographs.

Main outcome measures. The influence of method of cardiotocograph recording on inter-observer variation in respect of suggested management of the patient, as well as the observer's opinion of the duration of the recording.

Results. Variation in suggested management decreased significantly after assessment of the computer reports, compared with the standard cardiotocographs. While delivery was regarded to be indicated in 3.5% of patients and an immediate repeat of the cardiotocograph in a further 10%, no such action was proposed after evaluation of the computer reports of the same recordings.

Thirty-four per cent of tracings were considered to have been too long and 12.5% too short. However, suggested management in 40% of the latter cases seemed inappropriate for tracings regarded as of too short a duration.

Conclusion. While computer-assisted cardiotocographs significantly decrease inter-observer variation in the proposed management of patients, its cost-effectiveness in an obstetric special care unit in a developing country should be validated, as it might increase monitoring time.

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Antepartum fetal heart rate (FHR) monitoring is widely used for fetal surveillance, although its benefits have yet to be convincingly proved in randomised controlled trials. One of the most important deficiencies, which certainly contributes to inconsistencies between the test interpretation and eventual neonatal outcome, is the considerable inter- and intra-observer variation in assessment.[1,2] Repetition of the recording regularly assists in early diagnosis of fetal distress in some cases of abruptio placentae in patients with severe pre-eclampsia remote from term who are managed expectantly.[3] This approach requires meticulous observation of maternal and fetal condition, which is best achieved in an obstetric special care unit (OSCU).[4] Locally, we routinely repeat the non-stress test (NST) every 6 hours in these patients as abruptio placentae may develop suddenly, even in a patient who had a reactive NST earlier the same day. These tests are assessed by the registrar who rotates through the OSCU in consultation with one of the two consultants on call at the OSCU. Recently a cardiotocograph unit equipped with a programme for computer analysis of the FHR was established at our obstetric high-risk unit. Among the major reported advantages of this system, the Sonicaid System 8000, are the objective reporting of certain parameters which should facilitate management and the monitoring time which could possibly be saved.[5] It has also been demonstrated that the long-term as well as short-term FHR variability, as determined by the computer, correlate well with fetal condition. Prolonged low FHR variability has been associated with hypoxaemia, and progressive deterioration precedes fetal death.[5] Normal and abnormal values for long- as well as short-term FHR variability have been determined and validated.[5]

A study was undertaken to determine to what extent the method of cardiotocography and the reporting thereof influence inter-observer variation in interpretation as well as decisions on patient management, and also to define the place of the Sonicaid System 8000 in the cost-effective management of the high-risk obstetric patient.

Materials and methods

Permission was obtained from patients in the OSCU with severe pre-eclampsia to record the FHR simultaneously with the Hewlett-Packard model 8041 and the Sonicaid System 8000. The technique of acquiring and analysing the data has been presented in detail elsewhere.[6] In essence, the computer fits a baseline to the trace, recognises accelerations and decelerations according to their definition, and calculates the FHR range in milliseconds for each pulse interval of 3.75 seconds, referred to as an epoch. The overall long-term variability is indicated as the mean minute range (MMR) and is determined as the mean of the differences between the minimum and maximum epochal FHR range in each minute. An overall MMR of > 30 milliseconds is regarded as normal, between 20 and 30 milliseconds as equivocal and < 20 milliseconds as abnormal. The short-term variability is calculated as the mean of the FHR differences between each two successive epochs. The computer collects the information for as long as 60 minutes. Analysis is performed after 10 minutes and every 2 minutes

thereafter. Should the record appear normal at any stage according to the system's criteria, referred to as the Dawes and Redman criteria (DRC), advice is given to stop the recording. Alternatively, the advice to continue recording is given.

Termination of the recording in this study depended on the DRC of fetal well-being being fulfilled, and its duration was thus determined by the Sonicaid System 8000.[6] Twenty tracings were collected in each group. The purpose of the double recording was not revealed and the Sonicaid recordings were used for patient management. The registrars who, at the time of the study, had already worked in the OSCU since the introduction of the Sonicaid System 8000 were selected to participate in the study. The clinical situation given to participants was similar for each patient, to exclude other factors which might have influenced the management. The NST was said to have been that of a patient with severe pre-eclampsia at 32 weeks' gestation. Her condition was stabilised and the only reason for delivery would be the nature of the NST. The next NST would be recorded in 6 - 8 hours' time unless otherwise decided by the participant. Collaborators were asked to categorise each NST as reactive or non-reactive, or to state if they were uncertain. Appropriate action to be taken had to be outlined as immediate (either delivery or continuation of the NST with delivery as option if the pattern persisted or deteriorated) or routine (next assessment at a later stage either after 6 hours as suggested or at a later stage but earlier than the 6 hours as suggested). The length of recording had to be specified as too long if the recording could have been stopped earlier without influencing the categorisation of the NST, as too short if a decision could not yet be made, or as adequate if the recording was long enough to make a decision but a decision would not have been possible had the recording been stopped earlier. Two weeks later the computerised numerical reports were given to the 10 registrars. They were asked to state what their action would be, given the same clinical situation as before.

Proportions were compared using the χ^2-test, the odds ratio (OR) and 95% confidence limits (CL), or the Fisher exact test where numbers were small.

Results

Of the 199 reports based on own interpretation that were returned by the 10 participants, 83 were reported to be reactive, 94 non-reactive while in 22 cases there was uncertainty regarding the category (Table I). This classification significantly influenced the proposed management of the patient, with immediate action planned in 13 (13.8%) cases where the NST was regarded as non-reactive and in 14 (63.6%) where the physician was uncertain ($P = 1.85 \times 10^{-6}$, OR = 10.9, 95% CL = 3.44 - 35.88). This difference was even more significant when compared with reactive tests where no immediate action was planned ($P = 0.0008$ compared with non-reactive tests and $P < 10^{-6}$ compared with tests where the category was uncertain). No immediate action, either repeat of NST or delivery, was anticipated after evaluation of the Sonicaid System 8000 analysis of the same recordings. The difference in intended management from that suggested after assessment of the standard recordings was statistically significant ($P < 10^{-6}$) (Table II). When all 199 records available for analysis were considered, unchanged treatment was suggested in 137 cases, while more active management was proposed in 21 cases and more expectant management in 41 cases (Table III). Of the 27 recordings where prompt reaction was regarded as appropriate initially, 16 would now only be repeated after 6 hours and the remaining 11 later but in less than 6 hours' time (Table IV). In 5 of the 7 cases where delivery was originally considered to be warranted, routine management was considered sufficient after computerised analysis. In the remaining 14 cases where more expectant management was decided upon, a decision was taken to repeat the NST routinely instead of in less than 6 hours. More active management invariably involved repeating the NST at a later stage, but earlier than the 6 hours that were originally suggested.

Table I. Suggested management of patients according to physician's own interpretation of the CTG

	No immediate action required		Immediate action required	
Report category	Repeat CTG after 6 hrs	Repeat CTG before 6 hrs	Repeat CTG imme-diately	Deliver imme-diately
Reactive	83	0	0	0
Non-reactive	51	30	8	5
Uncertain of category	0	8	12	2
Total	134	38	20	7

CTG = Cardiotocograph.

Table II. Suggested management of patients according to the physician's interpretation of the computerised analysis of the CTG grouped according to the original report based on the Hewlett-Packard analysis

	No immediate action required		Immediate action required	
Original report category	Repeat CTG after 6 hrs	Repeat CTG before 6 hrs	Repeat CTG imme-diately	Deliver imme-diately
Reactive	73	10	0	0
Non-reactive	56	38	0	0
Uncertain of category	14	8	0	0
Total	143	56	0	0

CTG = Cardiotocograph.

Table III. Proposed management after evaluation of the computer analysis of CTGs compared with proposed management after own evaluation of standard CTGs

	Proposed new management		
Original category	More expectant	Unchanged	More active
Non-reactive	21	62	11
Reactive	0	73	10
Uncertain	20	2	0
Total	41	137	21

CTG = Cardiotocograph.

Table IV. Suggested management of 27 patients where immediate action was initially deemed necessary after the physician's interpretation of the computerised analysis of the CTG

Original report category and proposed management	Proposed management after evaluation of Sonicaid System 8000 analysis	
	Repeat after 6 hrs	Repeat later but before 6 hrs
Non-reactive (13)		
Repeat CTG	4	4
Deliver	4	1
Uncertain of category (14)		
Repeat CTG	7	5
Deliver	1	1
Total	16	11

CTG = Cardiotocograph.

In 12 of the 20 recordings analysed by the participants themselves, all 10 were unanimous that no immediate action was indicated. However, there was no unanimity in respect of those cases in which urgent action was deemed necessary. After the computer analysis became available, all individuals agreed that no immediate measures had to be taken ($P = 0.0016$).

Recording time was considered to have been adequate in 106 (53.3%) cases, too long in 68 (34.2%) cases and too short in 25 (12.7%) cases (Table V). However, in 10 (40%) cases where recording time was considered to be inadequate, no need was seen for immediate action (Table VI). Nine of these tests were reported to be non-reactive and in 1 case the NST was categorised as uncertain. In 8 of the remaining cases uncertainty prevailed regarding the category of the NST, while the other 7 were regarded as non-reactive. In the 22 cases where there was uncertainty about the category of NST, only 9 were considered to have been stopped too early and 11 to be of adequate length. Of the 12 cases among these 22 in which it was recommended that recording be repeated immediately, 4 were reported to have recordings of satisfactory length; 1 was even thought to have been too long.

Table V. Evaluation of duration of CTGs compared with initial categorisation of standard CTGs by a group of registrars

Category of CTG	Evaluation of duration of recording		
	Too long	Too short	Adequate
Non-reactive	37	16	41
Reactive	29	0	54
Uncertain	2	9	11

CTG = Cardiotocograph.

Table VI. Suggested management of patients according to physician's own interpretation of the duration of the CTG

Opinion on duration	No immediate action required		Immediate action required	
	Repeat CTG after 6 hrs	Repeat CTG before 6 hrs	Repeat CTG immediately	Deliver immediately
Too long	55	9	2	2
Too short	4	6	14	1
Adequate	75	23	4	4
Total	134	38	20	7

CTG = Cardiotocograph.

The median duration of the recordings was 18 minutes (range = 10 - 60 minutes) and the mean 30.39 minutes. The median duration of recordings regarded as too long (38 minutes, range 10 - 60 minutes) was significantly longer than the time of both those regarded as too short (18 minutes, range 10 -60 minutes) and those regarded as of adequate length (16 minutes, range 10 - 60 minutes). During the particular month during which the study was conducted, 453 NSTs were performed with the Sonicaid System 8000 in our OSCU. Of these, 60 (13.2%) had not met DRC at 60 minutes and 113 (24.9%) took more than 30 minutes to do so. One hundred and fifty-two (33.6%) met the DRC after 10 minutes. The median duration was 18 minutes and the mean 24 minutes.

Discussion

The major purpose of this study was to define the extent of inter-observer variation in interpretation of the NST and to assess the influence of computer-assisted analysis on the former, as well as their influence on decision-making in patient management. The absolute endpoint, namely perinatal outcome, was not assessed.

The availability of computer analysis significantly decreased inter-observer variation as far as the suggested management is concerned. Approach to management was more expectant, with 7 probable deliveries prevented. In 5 of these 7 cases routine repetition was recommended. After the computer analysis became available, there was complete agreement on the lack of indications for urgent intervention, no doubt the result of the numerical report of FHR variability together with guidelines supplied about the normality of the various parameters analysed by the computer programme.

It has been suggested that FHR monitoring might lead to increased interventions.[7] Indiscriminate use in pregnancies of 32 weeks' gestation or less might have serious consequences for neonatal units, especially where access to neonatal intensive care is limited, such as in the developing world. While it is gratifying that the Sonicaid System 8000 decreases inter-observer variation, any new system should be validated before being introduced into a population in which it has not been tested. The typical growth-retarded fetus of the mother with severe pre-eclampsia of early onset often illustrates a non-reactive pattern which is not necessarily a sign of fetal distress, but which could be an indication of fetal adaptation.[5,8]

Approximately one-third of the records were thought to have been of longer duration than was necessary for evaluation, meaning that the interpreter was of the opinion that the same clinical decision could have been taken at an earlier stage of the recording. Six (30%) of the 20 recordings used were 60 minutes long. The average duration was 30.39 minutes (median 18 minutes). As the length of recording was determined by the Sonicaid System 8000, this might lead to logistical problems if the new system is applied in the exact way as the old one, i.e. as much as 4 hours or more of recording time per patient per day. The same tendency was noted when all the recordings for the month were considered (mean = 18 minutes).

To classify the duration of the NST as too short is only

justified when the observer is still uncertain about the interpretation, or the fetus is judged to be in immediate danger. It would therefore be reasonable to expect that these tests would all be reported as of uncertain origin and that proposed management would be immediately to repeat the recording or to deliver the fetus. The fact that this was not the case in 10 (40%) of the 25 cases is difficult to explain but is probably due to inadequacies in the classification of NSTs or to inconsistencies in participants' decision-making. This is supported by the responses to the duration of records where the observer was uncertain of the category and felt that immediate repetition was indicated. It therefore seems that a report of too short a recording was justified by the proposed management in only 15 of the cases (7.4% of all cases). While these discrepancies could reflect on the level of experience of the interpreters, they apparently occurred only where the opinion was that a specific tracing was too short. Where the duration of a tracing was regarded as too long, the action seemed more appropriate. Three of the 4 cases where immediate action was considered necessary, in spite of the tracing's being regarded as too long (Table VI), occurred in patients where the DRC had not been met after 60 minutes. The participants felt that the variability was so poor that the tracings had been allowed to continue for too long before the doctor was called. It could possibly be argued that inconsistencies in response to recordings regarded as of too short a duration might reflect the inexperience of the interpreters. However, in such a case, it does not necessarily invalidate their opinion that specific tracing is too long, as it might also be reasoned that a cautious observer would be rather less inclined to give such a report. Obviously no definite conclusions can be made, but the question remains as to whether the proven benefit of decreased monitoring time with the Sonicaid System 8000 could be made applicable to our own circumstances. Clearly, more studies are needed.

The exact application of a computer-assisted cardiotocograph system in an OSCU in a developing country is not clearly defined. While it undoubtedly contributes to a reduction in the variation of proposed management by different observers, the possibility exists that it might take longer to perform if recording is to be continued till the DRC are met.

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