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FIGO News

Report of the FIGO Study Group on the Assessment of New Technology[1]

Evaluation and standardization of fetal monitoring*

The FIGO Study Group on the Assessment of New Technology in Obstetrics and Gynecology has established an Expert Committee, chaired by Professor Kazuo Maeda, to develop the following recommendations on the evaluation and standardization of fetal monitoring. These recommendations do not reflect an official position of FIGO.

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1. Introduction

The recommendations on the clinical use of a fetal monitor (cardiotocograph, CTG) were published in two FIGO News articles [1,2]. The present paper discusses the performance of a clinically applied fetal monitor from the viewpoint of electronic technology.

The equipment is basically composed of an ultrasonic Doppler autocorrelation fetal heart rate (FHR) meter, external tocodynamometer and a recorder of FHR and uterine contractions. The devices of FHR recorded by fetal direct electrocardiogram (ECG) and intrauterine pressure are included in a fully equipped fetal monitor. Some other components can be included in an expanded type of fetal monitor, e.g. the FHR meter which utilizes maternal abdominal lead fetal ECG and/or fetal heart sound, maternal heart rate meter, warning tone generator for the FHR decrease, the receiver of wireless telemetry, display panels for the FHR and uterine contraction data, the recorder of fetal movement, data memory, etc. Analog and digital output panels can be prepared for the utilization of electrical signals of FHR and uterine contractions. As for electrical safety of the fetal monitor, CF-class is adopted for the fetal ECG device and intrauterine pressure transducer [5]. Transducer surface temperature should be lower than 41°C [5].

2. Instantaneous heart rate meter

The beat-to-beat interval of electrical pulses generated by the peak detection of QRS of direct fetal ECG is measured in milliseconds (ms). The heart rates, which are successively represented by the values of 60 000 (ms) divided by each beat-in-

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terval (ms), are recorded on the chart and compose FHR pattern. Its standardization only needs the confirmation of accurate detection of QRS peak until 1 ms. The technique has been the most precise and the accuracy of other methods has been compared with the instantaneous heart rate.

3. Autocorrelation fetal heart rate meter

Although the instantaneous method is accurate in beat-to-beat change, the technique needs the attachment of a direct fetal scalp electrode for a precise QRS-peak detection, and therefore the monitoring is only applicable after the rupture of the membranes in labor. Autocorrelation heart rate meter is utilized throughout pregnancy and labor, irrespective of the state of the membrane, because the transducer is placed on maternal abdominal surface, and clear FHR is recorded even in labor, if ultrasonic Doppler fetal heart beat detection is combined with the autocorrelation.

The ultrasound Doppler fetal heart signals are processed by autocorrelation circuit of the fetal monitor because the shape of ultrasonic fetal heart signals delicately differs in successive heart beats. Although FHR pattern may be distorted due to inappropriate processing, the distortion must be minimum and should not influence the clinical evaluation. Therefore a fetal monitor is useful in clinical application, after the confirmation of reduced distortion by the tests of the monitor [3–5].

There are three major FHR changes which should be correctly recorded by a fetal monitor. They are: the discrete FHR value in every fetal heart beat, transiently increasing and decreasing FHR patterns, and the fast FHR changes (FHR variability, the oscillation) which is usually determined at FHR-baseline. The fastest change is beat-to-beat variation measured till 1 ms with direct lead of fetal ECG, although this measurement is difficult with other methods. Another fast FHR change of short duration is usually recognized on CTG records and it is also useful for the assessment of fetal well-being. Its disappearance (loss of FHR-baseline variability) usually shows depressed fetal condition. Standardization of the performance of fetal monitor on these parameters will minimize the possible interobserver difference.

4. The performance of the ultrasonic autocorrelation FHR meter

The ultrasonic transducer is flat and incorporates multiple crystals for wide area detection. Ultrasonic frequency is usually 1 MHz for the deep penetration and fetal heart beat is detected with a long pulse Doppler method. The ultrasonic intensity is limited to 10 mW/cm^2 or less [5] for the safety of the ultrasound. The fetal heart Doppler signals are introduced into autocorrelation circuit, FHR signal is obtained and recorded.

The tests of fetal monitor reported by Morgenstern [3,4] were carried out by various test signals, i.e., the moving steel ball which activated the transducer in the water, five QRS signals of direct fetal ECG derived from clinical monitoring and three artificial signals produced by computer. The method is a test of both FHR variability and discrete FHR value of the autocorrelation fetal monitor.

A standardization protocol of the fetal monitor recently proposed in Japan [5] is composed of the tests including the continuous FHR and various FHR patterns. As for the recording accuracy of continuous test signal, heart rate error measured on the recorded chart should be less than ± 3 bpm, compared to the input electrical signal with the cycle length of 1200, 600, 500 and 375 ms (error < 0.1%). The accuracy of the heart rate calibration generator should be within ± 0.5%.

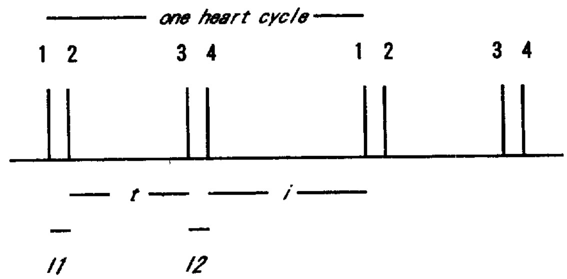

Fig. 1. Simulated fetal heart Doppler signal [5] used in the test patterns of Fig. 2. Pulse duration of each four signals are 10 ms. $I1$ (1–2) = 40 ms; $I2$ (3–4) = 65 ms; t (ms) = 268 − 0.85 FHR; i (ms) = 60 000/FHR − t + 105.

As for the recording accuracy of various FHR patterns, the test is carried out by mechanical signals similar to various FHR patterns generated by an actuator controlled by the computer system. The FHR patterns are formed by the test heart beat signals composed of the pulses which simulate the Doppler signals of fetal heart valves. Namely, its one cycle is composed of four pulses of 10-ms duration, the interval between the first and second pulses is 40 ms and that between the third and fourth is 65 ms; however, the interval between the second and third pulses (t) varies according to the FHR [6], i.e., t is expressed by the equation; t (ms) = 268 − 0.85 × FHR (bpm);

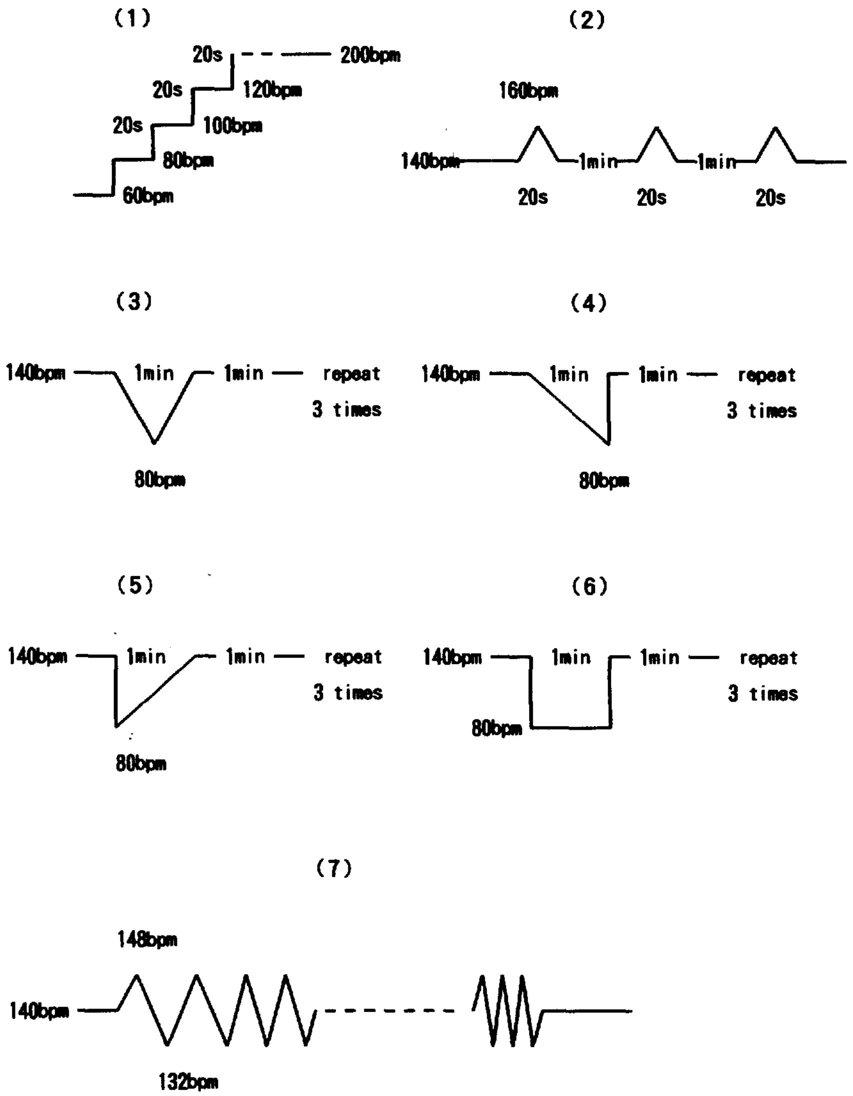

Fig. 2. Simulated FHR patterns generated by a computer-controlled actuator and used for the test of a fetal monitor [5]. Every beat of the pattern is composed of simulated Doppler fetal heart signals (Fig. 1). The patterns should be correctly recorded with the error smaller than the allowable levels (see text) [5]. The patterns show; (1) stepwise increases of heart rate; (2) simulated FHR accelerations; (3–6) simulated various types of FHR decelerations; and (7) simulated variabilities of 3–12 cycles per min.

and the interval between each heart beat also varies according to the FHR change (Fig. 1). The actuator action is conducted to the transducer by ultrasonic jelly inserted between the actuator and transducer. Simple QRS-like signals with changing intervals are used in the testing of direct fetal ECG device.

The wave forms, which simulated typical FHR patterns, are successively generated and actuate the transducer in the test (Fig. 2). The patterns recorded by the monitor should be as correct as the test signals, i.e. (1) in the staircase-like increase, the record should be ± 2 bpm of test signal at 5 mm after the increase, when the chart speed is 3 cm/min; (2) in the transient increase which simulates acceleration, recorded peak error should be within -3 bpm and the duration error ± 0.5 mm; (3) in the triangular decrease, the lowest level error should be within $+3$ bpm, the slope line error within 1.5 mm; (4–6) the error should be ± 2 bpm at 5 mm after sudden decrease or increase, slope line error within 1.5 mm; (7) in simulated FHR-baseline variabilities of 2–12 cycles per min (cpm), variability amplitude error should be smaller than 3 bpm in 2–8 cpm and the amplitude should be more than half of test signal at 12 cpm.

5. Measurement and recording of uterine contractions

Although intrauterine pressure measurement is accurate, it is applied only in labor and its application is difficult during pregnancy. Therefore guard-ring type transducers placed on the surface of maternal abdomen are common in external monitoring and widely utilised in clinical fetal monitoring. The performance of a uterine contraction transducer is proposed in a fetal monitor standard [5].

In the external uterine contraction transducer, strain gauge output of the transducer is amplified and recorded on the chart, therefore the drift due to temperature elevation after placing it on maternal body is the main problem of the transducer. The drift on the chart should be within 20% of the full-scale, 30 min after an environmental temperature rise from 25 to 35°C. The frequency characteristics of an external transducer-output amplifier is DC to 0.5 Hz. Recording linearity should be $\pm 5\%$ of full scale.

As for the intrauterine pressure transducer, the drift on the chart should be within 2.5%, 30 min after a temperature rise from 25 to 35°C. The frequency characteristics of the amplifier is DC to 1.0 Hz in the intrauterine pressure method. Recording linearity should be $\pm 2\%$.

6. Other useful techniques in fetal monitoring

6.1. Telemetry

Short distance telemetry means wireless transmission of fetal and uterine contraction signals from a maternal transmitter to the receiver of a fetal monitor via radiowave or laser. This allows ambulation of pregnant woman and more physiologic FHR recording than in the bedrest position. The utility of maternal ambulation during NST was confirmed in continuous and prolonged monitoring of high-risk fetuses. Telemetry may allow FHR testing to be more acceptable to patients who prefer not to be physically confined to bed or chair. Telemetry is also hopeful in the organization of centralized monitoring of many patients simultaneously in a room by a midwife and/or by computerized evaluation.

Long distance CTG telemetry utilizes a telephone line or personal computer network from the patient home to a consultation center where hospital staff may make an appropriate decision related to the clinical course. It is sometimes associated with the transmission of blood pressure and/or blood glucose level. Data compression and short time transmission are common in very long distance telemetry. Telefaxing of a CTG chart to the center is also useful when the fetal monitor stands at the patient's location.

6.2. Objective record of fetal movements

Ultrasonic Doppler fetal movement signals are recorded with the single ultrasound transducer of a fetal monitor in a separate channel simultaneously with FHR (fetal actocardiogram) [7] and by automatic event marking (kinetocardiogram).

6.3. Computer analysis of FHR and uterine contractions

Various conventional experts' systems [8–12] have been reported in; FHR diagnosis depended on the beat-interval difference [9]; the change in initial and actual FHR-baselines in low umbilical arterial pH [10]; and detailed intrapartum analysis of FHR and uterine contractions, with the use of FHR score and FD index as objective parameters to predict fetal outcome and umbilical pH [11,12].

In the other systems, FHR variations were analyzed by the probability distribution matrix [13]. Fractal analysis of FHR in a chaos system was studied, the results related to perinatal outcome were obtained, and it was shown that FHR was a developing fractal structure and that chaos theory is applicable to FHR evaluation [14]. The studies on artificial neural network analysis of intrapartum FHR reported objective evaluations with the probabilities into normal, suspicious or pathological outcome, as well as the intrapartum probability trendgram [15].

References

[1] FIGO News. Guidelines for the use of fetal monitoring. Int J Gynecol Obstet 1987;25:159–167.

[2] FIGO News. Intrapartum surveillance: recommendations on current practice and overview of new developments. Int J Gynecol Obstet 1995;49:213–221.

[3] Morgenstern J, Abels T, Hollbrugge P, Somville Th, Weis G, Westhues D, Wolf P. CTG-Geräte Test '93. Medizinische Einrichtungen der Heinrich-Heine Universität Düsseldorf, 1994.

[4] Fetal Monitor Test — a brief summary. Application note, Hewlett Packard, 1995.

[5] Japanese Industrial Standards Committee. Fetal monitors, JIS T 1303. Tokyo: Japanese Standard Association, 1994.

[6] Nakai T. Ultrasonic Doppler signals of human fetal heart. J Yonago Med Assoc 1973;24:319–336.

[7] Maeda K. Studies on new ultrasonic Doppler fetal actogram and continuous recording of fetal movement. Acta Obstet Gynaecol Jpn 1984;36:280–288.

[8] Arduini D, Rizzo G, Romanini C. Computerized analysis of fetal heart rate in normal and growth-retarded fetuses. In: Kurjak A, Chervenak FA, editors. The fetus as a patient, advances in diagnosis and therapy. London: Parthenon, 1994:289–297.

[9] Wickham PJD, Dawes GS, Belcher R. Development of methods for quantitative analysis of fetal heart rate. J Biomed Eng 1983;5:302–308.

[10] Van Alphen M, Waagenvoort AM, Van Geijn H. Quantitative intrapartum CTG analysis. In: Cosmi EV, Di-Renzo GC, editors. Current Progress in Perinatal Medicine. London: Parthenon, 1993:805–811.

[11] Maeda K, Arima T, Tatsumura M, Nagasawa T. Computer-aided fetal heart rate analysis and automatic fetal distress diagnosis during labor and pregnancy utilizing external technique in fetal monitoring. In: Lindburg AB, Kaihara S, editors. MEDINFO 80. Amsterdam: North Holland, 1980:1214–1219

[12] Maeda K. Computerized analysis nf cardiotocograms and fetal movements. Bailliere's Clin Obstet Gynaecol 1990;4:797–813.

[13] Koyanagi T, Yoshizato T, Horimoto N, Takashima T, Satoh S, Maeda H, Nakano H. Fetal heart rate variation described using a probability distribution matrix. Int J Bio-Med Comput 1994;35:25–37.

[14] Di Renzo GC, Montani M, Fioriti V, Clerici G, Branconi F, Pardini A, Indraccolo R, Cosmi EV. Fractal analysis a new method for evaluating fetal heart rate variability. J Perinat Med 1996;24:261–269.

[15] Maeda K, Noguchi Y. Neural network analysis of fetal heart rate. In: Cosmi EV, editor. The place for new technologies in gynecology, obstetrics and perinatology. Bologna: Monduzzi Editore, 1995:95–101.