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A Comparative Study of a New Cardiotocography Analysis Program

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Abstract— Cardiotocography (CTG) is a frequently used technique of fetal monitoring to evaluate the well being of the fetus during pregnancy and in labor. The surveillance technique depends on the analysis of characteristic fetal heart rate patterns and uterine contractions. Computerized analyses can mitigate the intra-observer and inter-observer variability of visual CTG recording explanation, decrease the examination time, and the need of additional tests for fetal health. Several studies also showed that the signal processing techniques could help to determine the fetal heart rate (FHR) patterns, but all of them were only suitable for physicians. Following the criteria and consensuses of National Institute of Child Health and Human Development in April 2008, we developed a LabVIEW based FHR and uterine contraction (UC) pattern analysis software. This software has great potential for home-care use. The signal processing methods utilized in this study are median filter and peak/valley detection method. The analysis performance was verified by nineteen pregnant women's data. The accuracy of FHR baseline, baseline variability, early deceleration, UC frequency and NST all reach 100%. The accuracy of acceleration frequency reaches 90%. The accuracy of late and variable decelerations reaches 95%.

I. Introduction

Cardiotocography (CTG) is a frequently used technique of fetal monitoring to evaluate the well being of the fetus during pregnancy and in labor. The surveillance technique depends on the analysis of characteristic fetal heart rate (FHR) patterns and uterine contractions. In CTG the Non-stress test (NST) is a widespread and effective screening test to identify whether fetuses are in immediate jeopardy of hypoxia. NST measures the FHR reactivity, which reflects the interaction between the sympathetic and parasympathetic tone of the fetal autonomic nervous system. The NST is considered reactive if there are two or more accelerations exceeding 15 beats per minute (bpm) amplitude and lasting 15 seconds or more in a 20-minute window after 32 gestational weeks, and 10 beats per minute amplitude and lasting 10 seconds or more before 32 gestational weeks [1]. A reactive NST is greatly reassuring, with a negative predictive value of 99.8% for stillbirths occurring within one week, after excluding lethal congenital anomalies and unpredictable causes of fetal death, such as sudden onset of placenta abruption, umbilical cord accidents, et al [2].

Prenatal telemedicine was first described in 1979 and was applied to transmit fetal monitoring data from regional hospitals to tertiary centers [3]. Before telemedicine, the CTG surveillance often required pregnant women to travel long distances to the hospitals, and it was especially stressful for patients who reside far from properly equipped health centers. Further studies found that home fetal monitoring was easy to learn and accepted by patients, and the tracings were adequately clear for clinical interpretation [4-8].

The conventional visual interpretation of CTG recordings is subject to high intra-observer and inter-observer variability [9-10]. Computerized analyses can obviate these restrictions and decrease the examination time and the need of additional tests for fetal health [11]. Several researches also showed that the signal processing techniques could help to determine the FHR patterns, but all of them were only suitable for physicians [12-14].

Following the criteria and consensuses of National Institute of Child Health and Human Development (NICHD) in April 2008 [15], we developed and assessed a new objective and quantitative CTG analysis program based on LabVIEW graphical software system for clinician decision assistance. According to the great system integration potential and friendly user interface, the achievement of this study could further help developing the home-care system.

II. Material and Method

A. Data collection

We conducted this study to compare the visual interpretation of intrapartum fetal heart rate tracings with our new analysis software at a tertiary referral center. Nineteen tracing records were acquired from pregnant women after admission to the labor and delivery unit. The inclusion requirements were as follows: (1) singleton gestation, (2) pregnancy $\geq$ 32 gestational weeks, and (3) admission for obstetric indication or entry into the active phase of labor (cervical dilatation $\geq$ 3 cm).

The continuous-wave Doppler ultrasound transducer is strapped to the abdomen of the pregnant woman. It is used to direct an ultrasonic beam towards the fetal heart and to sense Doppler-shifted echoes created by moving cardiac structures. Relative pressure within the uterus is measured using a

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tocodynamometer strapped to the abdomen in the area of the uterine fundus. The FHR and UC signals were recorded in the instrument and can be reloaded into PC.

B. Category indexes

NICHD has updated the newest indexes and standard for indentifying the categories of fetal heart rate and uterine contraction in 2008. The category indexes include FHR baseline, baseline variability, acceleration, deceleration, and NST. There are three tiers of categories. We arranged and listed the definition of each index and the category classifications in Table I.

FHR baseline and variability are the indexes, which indicate the main active condition of the fetus. The safe range of FHR baseline is from 110 bpm to 160 bpm. FHR baseline higher than 160 bpm for more than 10 minutes is called tachycardia and lesser than 110 bpm for more than 10 minutes is called bradycardia. Tachycardia and bradycardia would be the index of fetal distress. Baseline variability presents the activity of the fetus. Baseline variability is determined by the variance of FHR in one minute. Baseline variability between undetectable and 5 bpm is defined as minimal, between 6 bpm and 25 bpm is defined as moderate, higher than 26 bpm is defined as marked. Minimal and marked are dangerous symptoms, which represent that the fetus may be in low activity or distress condition. A hilly increase region in FHR is defined as acceleration. Accelerations should satisfy the condition: the variance of onset to peak should increase more than 15 bpm and last more than 15 seconds. NST depends on the acceleration frequency. Reactive NST is defined as there are two accelerations in twenty minutes, otherwise is defined as non-reactive. A deceleration, the valley appearing in FHR signals, is usually associated with the UC peak. There are three different categories of decelerations, including early, late, and variable decelerations. An early deceleration is defined as that from the onset to nadir is more than 30 seconds, and the duration of nadir to UC peak should be less than 18 seconds. The definition of a late deceleration is similar with early deceleration except that the duration is more than 18 seconds. Variable decelerations have several characters, including apparent abrupt decrease in FHR, the onset to nadir of FHR is less than 30 seconds, and decrease in FHR is more than 15 bpm. Moreover, these decelerations sometimes combine with each other..

Table I
The identification of category index and classification [15]

Index	Tier	Definition	Code
Baseline rate	bradycardia	<110 bpm	1
	tachycardia	>160 bpm	2
	normal	110-160 bpm	3
Baseline variability	Absent	>Undetectable & <5 bpm	4
	Minimal	<=5 bpm	5
	Moderate	6-25 bpm	6
	Marked	>25 bpm	7
Acceleration		15bpm & >15sec & >2 times/20min	8
Deceleration	Late	Onset to nadir >=30sec & lag time>= 18sec	9
	Early	Onset to nadir >=30sec & no lag time	10
	Variable	Onset to nadir <30sec	11
NST		Reactive	12
UC		appearance	13
Category I	Including all of 3, 6, 12; absent of 10, 11		
Category II	Including any of 1-(1∩4), 2, 4, 5, 7, 11∩(5or6),9∩6		
Category III	4∩(9or11or1)		

C. Analysis software

The analysis software was developed by graphic language LabVIEW 8.6. LabVIEW is a powerful language for commonly used clinical instruments which were made by different companies. It totally supports the main clinical used instrument brands, such as HP, GE, and Agilent. For integrating commercial personal used device, LabVIEW provides lots of toolkits which could help communicating with the device rapidly. Moreover, LabVIEW is also useful for developing a friendly user interface, which is a critical condition of home-care system.

The analysis procedure block diagram is shown in Figure 1. The typical FHR and UC signals are shown in figure 2(a) and 2(b), respectively. The FHR and UC signals usually mix with heavy noise, and in the worst case, one may lose the signals. Mixing with noise and losing the signal will cause difficulty for analysis of FHR and UC. The first step of analysis procedure is to de-noise and delete the losing signal part in FHR and UC by determining the continuous zero value. Next, we use median filter to estimate the main tendency of the signal in order to reduce the influence of suddenly raised peak and noise. We use valley and peak detection method to determine decelerations and accelerations before determining other indexes. The peak/valley detection method is based on an algorithm that fits a quadruple polynomial to sequential groups of data points. The nadir location of deceleration would compare with UC peak location in order to classify early, late, or variable decelerations. The acceleration frequency is also utilized to determine the reactive or non-reactive NST. To determine FHR baseline and baseline variability one should use the unfiltered signal but exclude

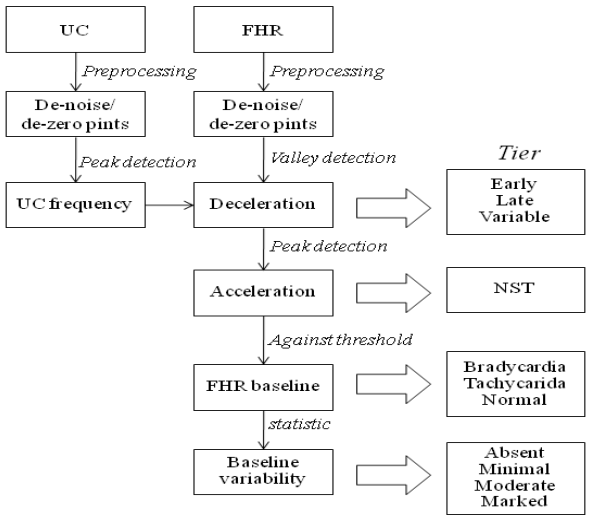

Fig. 1. The analysis procedure block diagram.

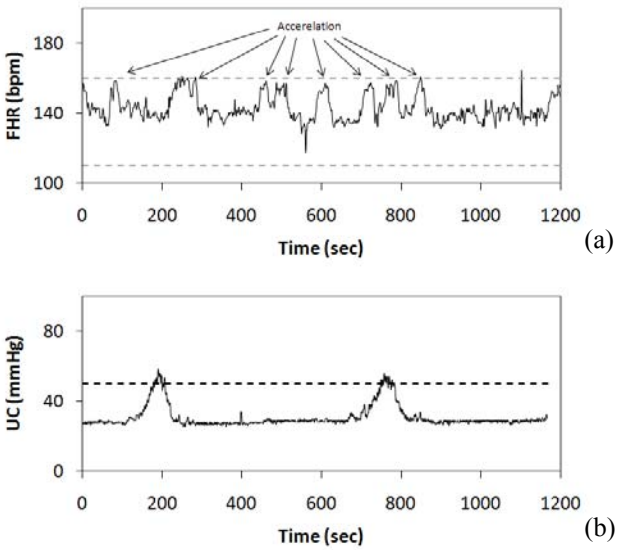

Fig. 2. The typical normal FHR and UC signal, (a) shows the FHR signal, (b) shows the UC signal

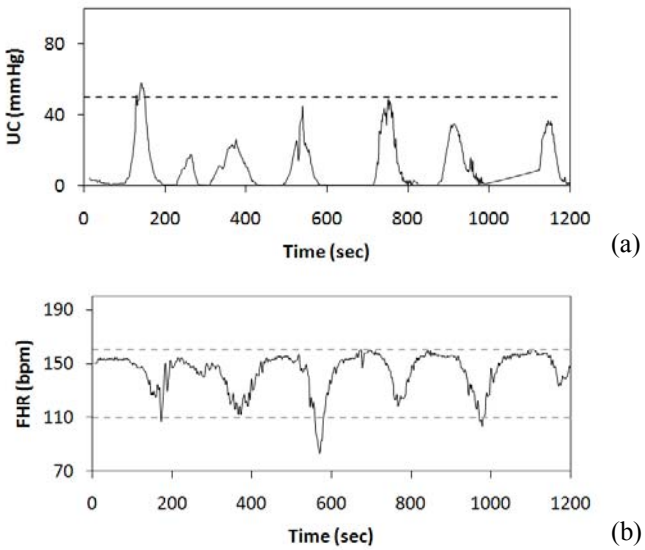

Fig. 3. The typical abnormal FHR and UC signal, (a) shows the FHR signal, (b) shows the UC signal

decelerations and accelerations. The analysis results were stored in MySQL database which allows users to check the records listed by Microsoft Access and Excel. The original measured FHR and UC data were also stored in the database.

III. Result and Discussion

Figure 2(a) and 2(b) show a normal case of the FHR and UC signals which was classified as Category I. There is no deceleration but eight accelerations in this twenty minutes record, which satisfies the condition of reactive NST. The acceleration is not a smoothly raised and descendent signal. It is usually composed with variation signal on the top of acceleration. The developed analysis software can successfully figure out the correct acceleration. The arrows in figure 2(a) point out the acceleration. The safe FHR baseline region is marked by a grey dotted line, which is between 110 bpm and 160 bpm. The FHR baseline of this case is all within the safe region. There are two sudden raised peaks appearing around 550th seconds and 1100th seconds. These peaks would not be dealt with baseline variability in the analysis software. The result shows that the baseline variability in this case is moderate. The UC frequency of this case is two and shown in figure 2(b).

A case with abnormal FHR and UC signals is shown in figure 3(a) and 3(b), which is classified as Category III. Obviously, there are several decelerations profiles appearing in the FHR graph, but none in normal graph. Compared with the peak locations appearing in Figure 3(b), this case has two early decelerations and four late decelerations, and three of four late decelerations composed with variable decelerations. The NST determination result shows this case is non-reactive. Baseline variability estimation would not include the region of acceleration and deceleration. Therefore, the baseline variability in this case is moderate.

This study verified the sensitivity of the analysis software by nineteen cases which were acquired from pregnant women after admission to the labor and delivery unit. The acquired FHR and UC signals were checked and classified by a physician before doing analysis processing. Each index had been calculated and estimated done by hand during this checking procedure. Ten cases had been classified as Category I by a physician, and nine cases had been classified as Category III. The tiering results of FHR baseline and baseline variability are 100% matched between the physician's estimation and computerized analysis results. The variety of FHR signals increases the determination difficulty in acceleration frequency estimation. Thirteen cases perfectly matched the physician's estimation results. The errors of other six cases were all controlled in one frequency and could be acceptable by physician. The accuracy in this study is defined as the ratio of miss/error value to total value. Therefore, the acceleration estimation accuracy reaches 90%. In the determination of deceleration, the cases classified as Category I have no deceleration. This result matches the physician's opinion. The early deceleration frequency estimation has 100% accuracy. Only one case falsely presents two late decelerations as variable decelerations. Therefore, the accuracy of late and variable deceleration estimation is 95%. The categorized and estimated results were plotted in Figure 4.

The front panel of the analysis software is shown in Figure 5. The figure on the left show the FHR and UC signals. The safe ranges are indicated by a dotted line. The table on the right side lists the analysis results, which is clear for recognizing and browsing. The original data and analyzed results were stored in MySQL database and could be reviewed in Microsoft Access and Excel.

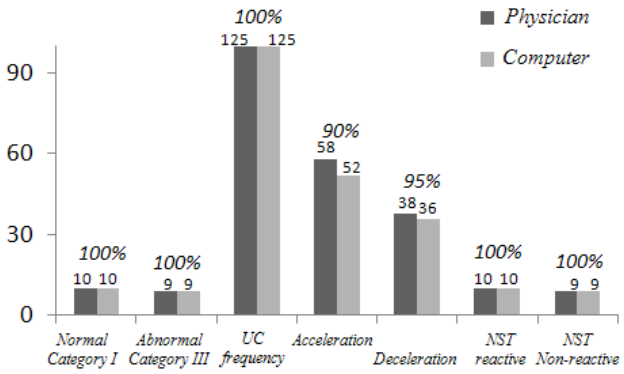

Fig. 4. The accuracy of computer analysis results.

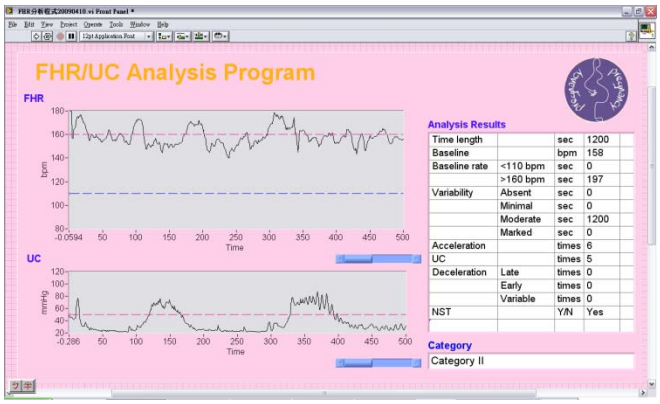

Fig. 5. The uster interface of the analysis software made in this study.

IV. Conclusion

In this study, we developed a LabVIEW based FHR and UC pattern analysis software and verified the analysis ability of the software by nineteen cases. The nineteen cases analysis results show that the correctness of FHR baseline, baseline variability, early deceleration, UC frequency and NST are all reaches 100%. The correctness of acceleration frequency reaches 90%. The correctness of late and variable decelerations reaches 95%. The design purpose of this software is suitable for monitoring the FHR and UC in home. The friendly user interface allows users to recognize their condition by reading the parameter and category lists. The software also has great potential of integrating with commercial instruments which are made by different industries. The measured FHR and UC signal and analysis results are stored in MySQL database and physicians can review the data on Microsoft Access and Excel directly.

References

[1] Electronic Fetal Heart Rate Monitoring: research guidelines for interpretation. National Institute of Child Health and Human Development Research Planning Workshop. Am. J Obstet. Gynecol., 1997, vol 177, pp. 1385-1390.

[2] ACOG Practice Bulletin: Antepartum fetal surveillance: Number 9, October 1999 (replaces Technical Bulletin Number 188, January 1994) Clinical management guidelines for obstetrician—gynecologists. Int. J Gynaecol. Obstet., 2000, vol 68, pp. 175-185.

[3] F. H. Boehm, and M. F. Haire, "Xerox telecopier transmission of fetal monitor tracings: a 4-year experience," Obstet. Gynecol.vol 53, pp. 520-523, Apr. 1979.

[4] D. B. Acker, M. Corwin, B. P. Sachs, and E. Schulman, "The nonstress test. transmission from the home," J Reprod. Med., vol 34, pp. 971-974, Dec. 1989

[5] R. W. Naef, J. C. Morrison, J. F. Washburne, B. N. McLaughlin, K. G. Jr Perry, and W. E. Roberts, "Assessment of fetal well-being using the nonstress test in the home setting," Obstet. Gynecol., vol. 84, pp. 424-426, Dec. 1994.

[6] H. Horio, M. Murakami, Y. Chiba, and H. Inada, "Fetal monitor for non-stress-test screening at home," Biomed. Instrum. Technol, vol. 32, pp. 39-47, Jan-Feb 1998.

[7] R. Kerner, Y. Yogev, A. Belkin, A. Ben-Haroush, B. Zeevi, and M. Hod, "Maternal self-administered fetal heart rate monitoring and transmission from home in high-risk pregnancies," Int. J Gynaecol. Obstet., vol. 84, pp. 33-39, Jan 2004

[8] A. Di Lieto, M. De Falco, M. Campanile, R. Papa, M. Torok, and M. Scaramellino, "Four years' experience with antepartum cardiotocography using telemedicine," J Telemed. Telecare., vol. 12, pp. 228-233, 2006

[9] L. D. Devoe, "Nonstress testing and contraction stress testing," Obstet. Gynecol. Clin. North Am., vol 26, pp. 535-556, Dec 1999

[10] J. Bernardes, A. Costa-Pereira, D. Ayres-do-Campos, H. P. Van Geijn, and L. Pereira-Leite, "Evaluation of interobserver agreement of cardiotocograms," Int. J Gynecol. Obstet., vol 57, pp. 33-37, Apr 1997.

[11] L. A. Bracero, S. Morgan, and D. W. Byrne, "Comparison of visual and computerized interpretation of nonstress test results in a randomized controlled trial," Am. J Obstet. Gynecol., vol 181, pp. 1254-1258, Nov 1999

[12] G. M. Taylor, G. J. Mires, E. W. Abel, S. Tsantis, T Farrell, P. F. W. Chien, and Ying Liu, "The development and validation of an algorithm for real-time computerized fetal heart rate monitoring in labour," BJOG: An International Journal of Obstetrics & Gynaecology, vol 107, pp. 1130-1137, Sep 2000.

[13] A. D. Lieto, U. Giani, M. Campanile, M. D. Falco, M. S.caramellino, and R. Papa, "Prenatal telemedicine: clinical experience with conventional and computerized antepartum telecardiotocography," Eur. J. Obstet. Gyn. R. B., vol 103, pp.114-118.

[14] G. Magenes, M. G. Signorini, M. Ferrarion, and F. Lunghi, "2CTG2: A new system for the antepartum analysis of fetal heart rate," Medicon 2007, IFMBE Proceedings 16, pp. 781–784, 2007.

[15] G. A. Macones, G. D. Hankins, C. Y. Spong, J. Hauth, and T. Moore, "The 2008 National Institute of Child Health and Human Development workshop report on electronic fetal monitoring: update on definitions, interpretation, and research guidelines," Obstet. Gynecol., vol. 112, pp. 661-666, Sep 2008.