VOL II

Ciências da Saúde:

Investigação e Prática

Guillermo Julian Gonzalez Perez
María Guadalupe Vega-López
(organizadores)

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PRÓLOGO

La investigación de los problemas de salud y enfermedad desde diferentes perspectivas teóricas y metodológicas cobra especial relevancia en la búsqueda de respuestas que -llevadas a la práctica- permitan implementar acciones que redunden en la mejora de la calidad de vida de la población. El enfermo, la familia, el cuidador, el profesional de la salud o la población en general son, así, protagonistas de los trabajos que se exponen en el presente documento, los cuales -desde distintas disciplinas como la medicina, la enfermería, la psicología o la epidemiología, entre otras- se enfocan en temas oportunos y pertinentes para la práctica sanitaria.

En tal sentido, aspectos tales como el tratamiento de padecimientos y su relación con la calidad de vida del paciente, el papel de la familia en el cuidado de la salud, la pandemia de COVID 19 y sus distintas implicaciones para los adultos mayores, la situación de los cuidadores, la utilización de la tecnología para la detección oportuna de problemas en el embarazo, la educación ambiental en los programas de estudios en el campo de la salud o la experiencia del profesional de la salud en el papel de enfermo son algunos de los tópicos que - utilizando tanto técnicas cuantitativas como cualitativas- se exploran en este documento.

El presente volumen, segundo de la serie Ciencias de la Salud: Investigación y Práctica, está compuesto por 12 capítulos que se concentran en seis ejes temáticos: Salud Familiar y Comunitaria, Enfermedades, Tratamientos y Calidad de Vida, Enfermedades Infecciosas, Salud Mental y Cuidados, Tecnología y Salud y Salud y Educación. Esta forma de organizar el libro ofrece a los lectores la posibilidad de detenerse a examinar con más detalle cada una de estas temáticas y de igual modo, permite hallar con mayor facilidad trabajos que coinciden en su objeto de estudio o en el contexto particular en que se desarrollan.

Autores de Chile, España, México y Portugal colaboran con sus artículos en esta obra, brindando a los interesados en las ciencias de la salud la oportunidad de acercarse a la situación sanitaria que viven los países iberoamericanos y las realidades y desafíos a los que se enfrentan. Convidamos a los lectores interesados en esta área del conocimiento a revisar los distintos capítulos de este documento, esperando que el mismo satisfaga sus expectativas.

Dr. Guillermo Julián González-Pérez

Dra. María Guadalupe Vega-López

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ASSESMENT OF FETAL HEART RATE VARIABILITY COMPUTATION ALGORITHMS BY DEVELOPING A STAND-ALONE DEVICE FOR SIMULTANEOUS RECORDING OF CARDIOTROCOGRAPHY BIOSIGNALS

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ABSTRACT: Fetal hypoxia/acidemia recognition improves with computerized analysis of biosignals collected from cardiotocography (CTG), particularly the assesment of short-term variability (STV) of fetal heart rate (FHR). Several methods to compute STV have been described with diverse performance results according to acquisition method, sampling and storage rates and algorithm definition. Dawes-Redman algorithm (STV16) is the most widely reproduced in available commercial systems. However, it shows a low correlation with the beat-to-beat variation determined from fetal electrocardiographic signal (fECG). STV240 algorithm has been introduced in an attempt to approximate STV assessment to real beat-to-beat variation. There is no comparison in the literature between these two algorithms, taking as gold standard variability obtained from ECG tracing. With a view to providing reliable records for the standardization and comparison of STV algorithms, most notably, STV16 and STV240, we have designed, assembled and developed a stand-alone device well able to connect with different CTG machines and collect simultaneously biomedical signals of interest, particularly FHR, uterine activity and fECG, from the standard monitor outputs. It generates a file in an open format that allows assessment of computerized parameters of CTG. By means of R-R instantaneous variation from fECG as a reference we have found no agreement by Intraclass Correlation Coefficient between STV16 and STV240, neither with STV calculated from fECG. Nevertheless, the last two correlated closely. Standardisation of

algorithms, interoperability and research in computerized CTG need to be provided with simultaneous recordings of biosignals involved, including the ECG raw signal. STV16 and STV240 require individualised normal ranges.
KEYWORDS: Cardiotocography. Fetal electrocardiography. Short term variability. Fetal distress.

1 INTRODUCTION

The main objective of intrapartum obstetric surveillance is to diagnose fetal hypoxia/acidemia to prevent brain damage or perinatal death by means of adequate obstetrical interventions. Fetal monitoring by cardiotocography (CTG) is the most widely used technique to identify fetal compromise. It simultaneously records fetal heart rate (FHR) and uterine contractions (uterine activity -UA-). Most common methods of acquisition of FHR are:

1.1 EXTERNAL DOPPLER ULTRASOUND MONITORING:

Mechanical activity of fetal heart is detected by means of a transducer applied on the maternal abdomen. It estimates FHR by an autocorrelation technique on Doppler envelope which recognises shape similarity. This function tends to average the durations of successive cycles.

1.2 INTERNAL ELECTROCARDIOGRAPHIC MONITORING:

Fetal electrocardiographic (ECG) signal during labour through an electrode attached to the foetus is recorded. FHR is calculated from duration of fetal cardiac cycles, obtaining interval between consecutive R-waves. It is the reference technique because it ensures the highest accuracy of heart interval measurement. It can only be used during labor, after the rupture of membranes and the beginning of cervical dilatation.

These approaches to compute STV have different performance and the trace acquired is not exactly the same. Using direct ECG acquisition we can obtain the exact duration of the cardiac cycle and therefore the instantaneous FHR (Cesarelli *et al*, 2009; Wretler *et al*, 2016).

CTG has low levels of inter-observer and intra-observer reproducibility when a human visual interpretation is applied, particularly on long records with a large amount of information. Its low specificity leads to unnecessary interventions that increase caesarean section and operative vaginal delivery rates. This issue can be solved by an objective numerical analysis of relevant CTG features, which requires computerisation

of the signals obtained from the CTG device. Interpretation of the recording without the support of these parameters is inadequate for appropriate care in high-risk pregnancies (Bilardo *et al*, 2017), and their inclusion improves perinatal outcome (Lopes-Pereira *et al*, 2019).

The challenge of contractions during labour often leads to changes in FHR most commonly due to adrenergic stimuli or vagal reflexes, and less often to hypoxia caused by restricted gas exchange over the placenta. Obstetric interventions would only be necessary in case of severe hypoxia, which occurs in only 1% of births. The right identification of such cases needs more accurate interpretation methods.

Several methods of computerized analysis have been proposed. The most valuable is the calculation of short-term variability (STV). It is the beat-to-beat variation in fetal heart rate: expresses the difference between time intervals separating fetal heartbeats, which can be expressed either in time between beats (milliseconds) or in the frequency of those events in a predetermined time span (usually in beats per minute –bpm-).

Low STV predict severe chronic hypoxia and intrauterine fetal death in pre-delivery monitoring (Grivel *et al*, 2012). However, most studies that have so far evaluated the usefulness of STV analysis in the identification of intrapartum fetal distress have not found it helpful in the identification of fetal acidosis (Lu *et al*, 2018).

There are different STV analysis methodologies,

1.3 TIME DOMAIN METHODS:

Dawes-Redman algorithm (STV16) is the most widely reproduced in market systems (Wretler *et al*, 2016). It calculates STV by dividing each minute into 16 segments, each one being 3,75 seconds long. The average pulse interval in each section is calculated and the STV16 derives from the difference of the average pulse intervals between two sections. Every STV16 epoch includes 7-10 fetal heartbeats or 6-9 pulse intervals what means its value does not exactly match with the beat-to-beat variation of the FHR.

Algorithm STV240 has been proposed in an attempt to approximate the actual beat-to-beat variation considering that dividing the pulse interval into smaller fractions achieves a more accurate approximation. It has been implemented in the commercial system Philips IntelliSpace Perinatal™ (Amorim-Costa *et al*, 2016).

STV240 and STV16 are correlated although values of the STV240 were significantly lower in comparison to the ones of the STV16. Normal values vary according to the algorithm applied (Kouskouti *et al*, 2018).

1.4 FREQUENCY DOMAIN METHODS:

Most studies about spectral analysis of FHR have shown the ability to identify states of fetal acidosis, in particular LF/HF ratio of FHR variability (Castro *et al*, 2021). Nevertheless, a standardized definition of parameters in this domain is still lacking and subject to changes and updates.

Traditional analysis lack of broadly supported methods for computing time or frequency domain indexes (Romano *et al*, 2016). To investigate the predictive ability of STV assessment during labor to identify fetal distress we need to have the appropriate reference values according to the signal acquisition method and STV calculation algorithm applied (Wretler *et al*, 2016). Indeed, calculation of time series of STV differs according to the source of data, external or internal monitoring. The external Doppler ultrasound acquisition is usually sampled at 4 Hz and has a resolution of 1 bpm, while the ECG-based is a continuous variable sampled at 500-1000Hz. Comparison of algorithms needs simultaneous recordings with direct fetal electrocardiography (Jezewski *et al*, 2006).

We therefore need to simultaneously obtain the FHR traces obtained from internal and external monitoring together with the fetal ECG signal as a reference in order to have adequate data to objectively identify the most effective algorithms for the assessment of STV.

For this purpose, we have developed an electronic device that allows the simultaneous acquisition of the biomedical signals generated by the CTG machines together with the fetal ECG signal, which generates .dat files that allows the calculation of computerised parameters of the cardiotocographic monitoring, in particular the STV, taking as gold standard the beat-to-beat variability obtained from the fetal electrocardiographic tracing.

2 OBJECTIVES

2.1 To design, assemble and develop an autonomous electronic device to allow for the collection of biosignals from different cardiotocograph models. The device collects simultaneously biomedical signals of interest (particularly fetal heart rate, uterine activity and fetal ECG signal) from the standard outputs of the monitor and generates a file in an open format that allows the calculation of computerized parameters of CTG monitoring.

2.2 To establish the accuracy of STV16 and STV240 algorithms assessed from external Doppler ultrasound CTG, taking as gold standard the beat-to-beat variability obtained from the fetal ECG signal.

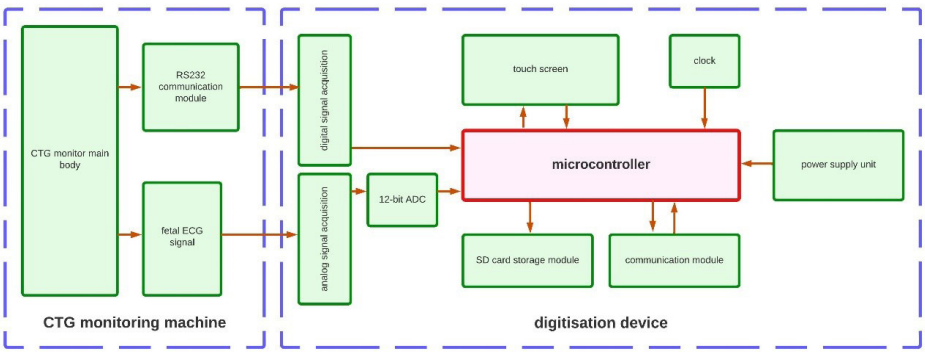
3. MATERIAL AND METHODS

3.1 IMPLEMENTATION OF THE DIGITIZING DEVICE (DD)

3.1.1 System Functional Description

We have designed, assembled and developed an energy and operationally autonomous device –it not require a connection to a computer for its operation- able to connect with different cardiotocograph models to collect simultaneously biomedical signals of interest (particularly fetal heart rate, uterine activity and fetal electrocardiographic signal) from the standard outputs of the monitoring machine. It generates .dat files that allows the calculation of computerised parameters of the cardiotocographic monitoring, in particular the STV taking as gold standard the beat-to-beat variability extracted from the fetal electrocardiographic tracing. Corometrics 250™ cardiotocographic machine was the equipment employed for the present project. In figure 1 we represent the functional block diagram of the device.

Figure 1. Functional block diagram.



Input:

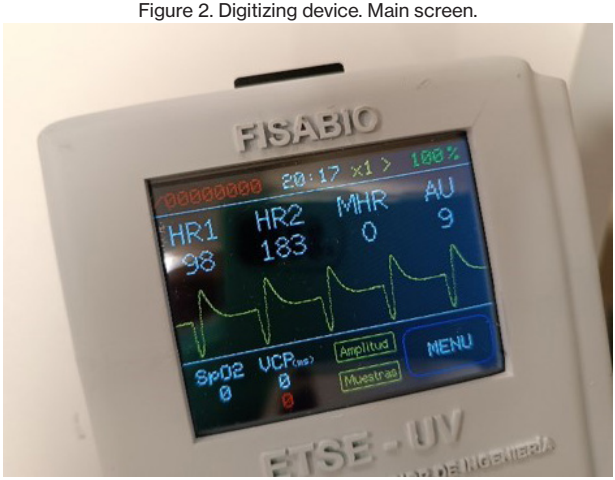
- **Digital signal**: Corometrics 250™ (fetal monitor –FM-, in this case as Data Terminal Equipment –DTE-) has three RS232 Serial Communication Protocol ports. In response to a request command coming from the host digitizing device –DD- (as Data Communications Equipment –DCE-) the FM starts the sending of data blocks every 990 to 1100 milliseconds each containing four values of two-channel of FHR (HR1 and HR2) and four values of the abdominal wall pressure collected by the external pressure transducer monitoring uterine activity (UA), as well as others related to maternal biophysical parameters. HR1 is obtained from the fetal ECG signal but it is delivered with a resolution

of 1 bpm and updated every 250 milliseconds, thereby not actually reflecting instantaneous FHR. HR2 is the FHR estimated from the Doppler signal obtained by the external US transducer. In this case, the signals are also sampled at 4 Hz and have a resolution of 1 bpm. AU is likewise sampled at 4 Hz and has a resolution of 1 mmHg. A converter module RS-232/TTL enables the microcontroller to receive the data blocks.

- **Analog signal**: Corometrics 250™ has an analog output for maternal ECG and fetal ECG signals. Fetal ECG signal has a bandwidth of 100 Hz with an amplitude of 10 V/mV. A sample rate of 1 kHz was chosen, wich meets the requirement of 2*F.max<=Fs. With the ADS1015 12 bits ADC converter resolution is of 0.8 mV.
- ***Interactions:*** three consecutive menus operated on the touch screen provide access to the device's functions:
    - First menu allows to start the telematic updating process of the time and software
    - Screen for entering the identification of the pregnant woman
    - Menu of specific functionalities: starting a new case, starting a new file, sending the request command.
- ***Data handling and storage***: raw data from data blocks are extracted, decoded and stored. Each monitoring generates a folder on the memory card whose name is the identification number of the pregnant woman. A folder with the date on which it was created is generated inside it, so that if other CTG testing is performed on different days, they are all stored in a single folder for each pregnant woman. Every time the user clicks on the "Fichero nuevo" menu button a folder identified with the start time of the recording is generated in a lower level, containing four files:
    - cabecera_FicheroAnalogico.dat: it saves 10 data of which 7 are of type uint8_t and 3 of type int16_t with information of date and time of registration, ADC resolution, maximum and minimum ADC voltage (mV) and sampling rate (Hz).
    - cabecera_FicheroDigital.dat: it saves 8 type data uint8_t that correspond to date and time of registration, digital sample rate and number of channels.
    - ficheroAnalogico.dat: it contains the voltage value of the fetal ECG signal scanned at a sampling rate of 1 kHz.

- ficheroDigital.dat: it contains the information corresponding to the following signal channels provided by FM: HR1, HR2, UA, Maternal NIBP (non-invasive blood pressure measurement), Maternal SpO2 (maternal oxygen saturation level), MHR (maternal heart rate).

Figure 2. Digitizing device. Main screen.



Output

Figure 2 shows the device operating in simulation mode.

- **Display of digital data on screen**: data extracted from bloks are displayed on screen: HR1, HR2, MHR, UA and SpO2. Also STV is calculated in real time following Dawes-Redman criteria and displayed on screen. Additional information is also shown: identification number of the case, time and battery charge level. An additional button allows access to the menu to start a new case, a new file or send the request command.
- **Display on screen of analog signal of fetal ECG**: it is displayed in refreshing or still mode. Complementary buttons allow to try the scale and the number of samples displayed.

3.1.2 System Technical Specification

In figure 3 we represent the wiring diagram.

Microcontroller

The microcontroller used is the ESP32, chosen by its ultra-low power consumption, integrated Wi-Fi and to be able to receive updates by FOTA (Firmware Over-The-Air). It is

small and compatible with a large number of libraries. The CPU speed can reach 240 Mhz and is easy to programm with the Arduino IDE.

Touchscreen

ILI9341 LCD TFT is a 3.2-inch screen that integrates a resistive touch sensor controlled by the XPT2046 chip that increases its accuracy. It integrates an SD card module allowing to save space in the device. It can be powered with 3.3V or 5V and its consumption is quite low.

Powering

A 18650 battery and battery charging module provides the device with an autonomy of between 6-10 hours of use. Microcontroller programming: the IDE (Development Environment) is the Arduino IDE V 2.0.0.

Testing

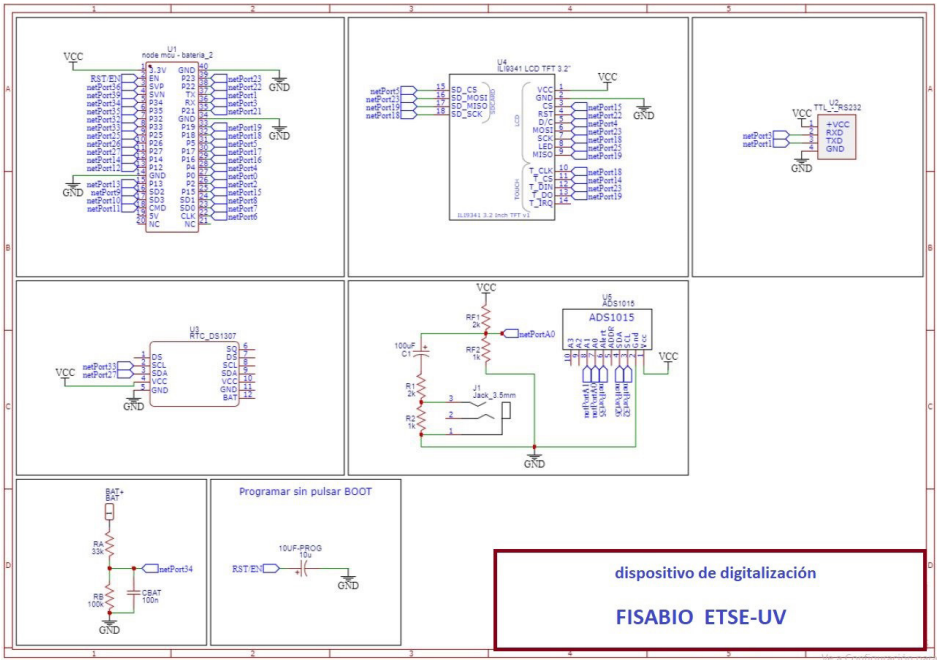
A DYNATECH-NEVADA 215A Patient Simulator and a digital oscilloscope were used to establish the accuracy of the fetal ECG signal recording. The integrity of the data recorded from the data blocks issued by the FM was checked by means of a commercial RS 232 recorder (AirDrive RS-232 Recorder) connected in series between FM and DD.

Specific features of security

In order to ensure functional robustness and facilitate easy handling by healthcare professionals, reducing to a minimum the number of operations to be performed on the DD once it is connected and guaranteeing the generation of the corresponding files the device performs some security actions:

- After powering up the device, it automatically sends a request command to start communication through the RS232 port. If the wired connections from the FM to the DD are done with the device switched on, communication can be initiated manually via a menu option on the touch screen.
- To end the digitalisation of a CTG monitoring section and start a new one on the same pregnant woman, it is only required to activate the “Fichero Nuevo” option in the touch screen menu.
- Turning off the device triggers the storage of the scan in progress, therefore it is not necessary to press any specific button that generates the file.

Figure 3. Wiring diagram.



System updating

The device has to connect to a Wi-Fi network to check if there is an update or not via a smartphone to share the connection. If an update is available, operator immediately receives a warning and the device will download and install new firmware. When the process is finished it will restart automatically.

3.2 COMPARISON OF METHODS OF STV ASSESSMENT

3.2.1 Population

Ten consecutive CTG records digitised with the DD in single pregnancies who underwent internal monitoring on clinical indication during June-July 2023 were included. Digitalisation was carried out from the start of internal monitoring until delivery (duration between 10 and 260 minutes).

For the comparison of the STV16 and STV240 algorithms on external Doppler monitoring we studied the fragments where the twin mode of FM was employed (external and internal monitoring on the same pregnant woman). It allows collect simultaneously FHR from external Doppler monitoring, FHR from internal monitoring, uterine activity and fetal electrocardiographic signal. A total of 52 minutes of recording time was used for this

purpose. STV16 and STV240 groups were compared with instantaneous STV values from ECG signal (ecgSTV).

Instantaneous variability of FHR from ECG signal was calculated from time between R peaks of consecutive waves. Matlab findpeaks function (wich identifies values and locations of local maxima) was employed to find them. These values were averaged by the minute to obtain a format in accordance with those achieved with STV16 and STV240 algorithms. Calculations were done on the entire record without removing fragments with episodic changes from the baseline. Artefacts were ruled out by disregarding instantaneous FHR variation values greater than 25 bpm.

Institutional review board approval was obtained.

3.2.2 Statistics

Mean values of STV16, STV240 and ecgSTV groups were compared by paired samples t-test. The agreement between series was evaluated by means of Intraclass Correlation Coefficients (ICC, McGraw *et al*, 1996). The A-1 version shows degree of absolute agreement and C-1 the degree of consistency among measurements. Also, Bland-Altman plots were depicted. For all statistical tests, a significant level of 0.05 was pre-defined. Calculations were computed in MATLAB R2023b.

4 RESULTS AND DISCUSSION

The DD developed is able to acquire FHR traces obtained from internal and external monitoring together with the fetal raw ECG signal as a reference in order to have adequate data to calculate computerised parameters. Fetal ECG signal allows calculation of the actual instantaneous STV. Figure 4 compares the instantaneous STV between two cases with good and bad perinatal outcome. Therefore, simultaneous recording of all biomedical signals of interest allows to assess the agreement of the algorithms used to estimate STV (STV16 and STV240) in external monitoring with that obtained from the fetal ECG raw signal.

Figure 4. Comparison of STV acquired from ECG signal between two cases with good perinatal outcome and severe neonatal depression.

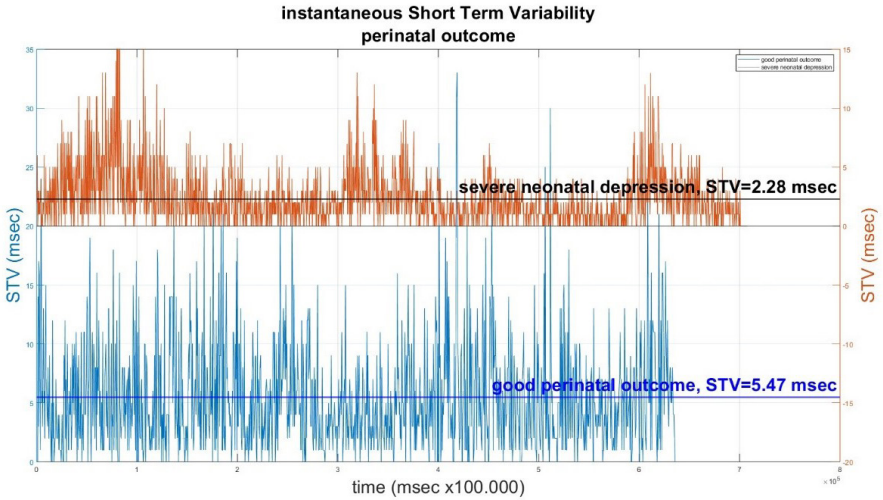


Figure 5 shows close similarity between the CTG monitoring trace with instantaneous FHR obtained from the fetal ECG signal taken as the basis of comparison (top), and the two traces extracted from the external US monitoring and the internal monitoring, sampled both at 4 Hz by the FM (bottom). US Doppler monitoring trace is slightly delayed in relation to the internal monitoring trace because of the methodological extraction of the former (autocorrelation technique on Doppler envelope) which tends to average the durations of successive cycles.

Figure 5. Comparison of traces acquired from ECG signal, US Doppler and internal monitoring. Magnified view in the center of the figure.

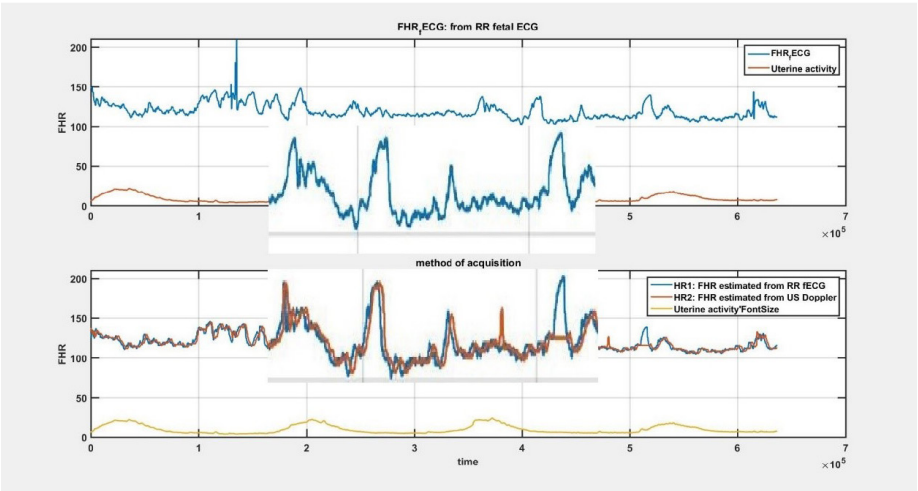
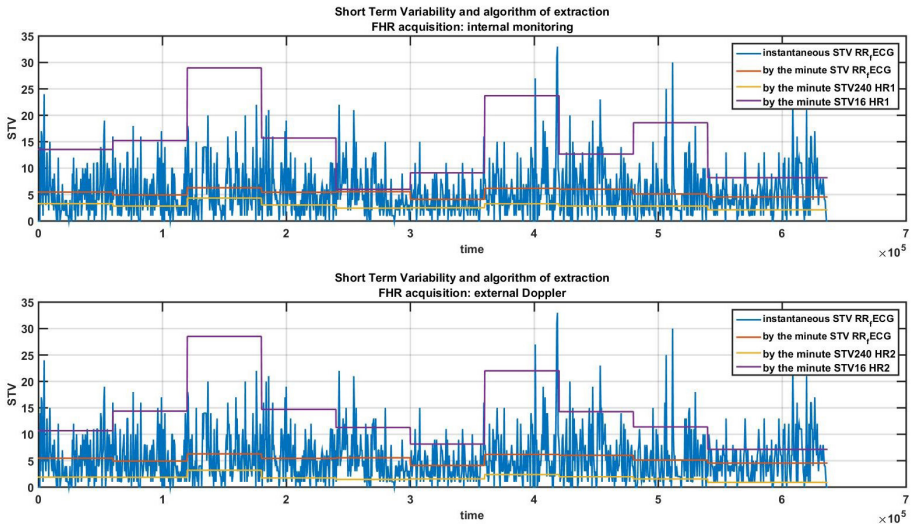


Figure 6 shows instantaneous STV calculated from fetal ECG signal compared to this same averaged by the minute and with by the minute-STV extracted by means STV16 and STV240 algorithms for HR1 and HR2 channels in a trace of ten minutes of a case with normal perinatal outcome, corresponding to the tracing in figure 5.

Figure 6. Comparison of STV (msec.) from: instantaneous variability (fetal ECG signal), average by the minute and STV16 and STV240 algorithms: top internal monitoring, bottom down US Doppler.



Mean values of STV16, STV240, ecgSTV groups from US Doppler signal were: 9.85 (+/-8.62), 2.22 (+/- 5.57), 3.68 (+/- 2.25), respectively. Paired samples t-test shows no difference between STV240 and stvECG. Nevertheless, STV16 is significantly higher than STV240 and stvECG. Our results are similar to those described in the literatura (Kouskouti *et al*, 2018)

Table 1. Consistency among measurements.

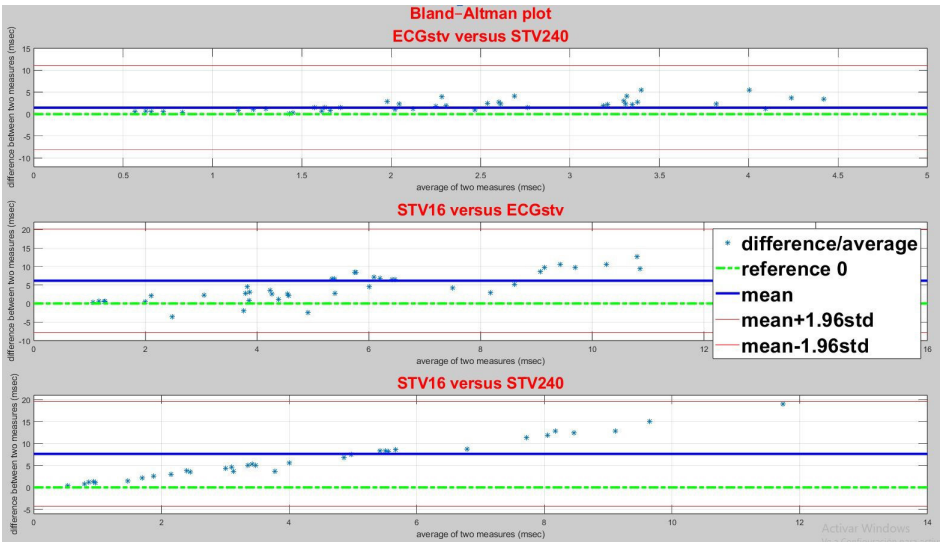
Consistency	ICC C-1	confidence interval 95%	p
ECGstv *versus* STV240	0.33	0.04-0.57	**0.01**
ECGstv *versus* STV16	0.36	0.07-0.59	**<0.01**
STV240 *versus* STV16	0.65	0.44-0.79	**<0.01**

Table 2. Agreement among measurements.

Agreement	ICC A-1	confidence interval 95%	p
ECGstv *versus* STV240	0.32	0.04-0.56	**0.01**
ECGstv *versus* STV16	0.24	-0.05-0.51	0.06
STV240 *versus* STV16	0.42	-0.09-0.73	0.07

Tables 1 and 2 describe the level of reliability of STV measurements carried out by the STV16 and STV240 algorithms with regard to values calculated from the ECG by Intraclass Correlation Coefficients. All C-1 ICCs become significant for p=0.05 (all series show consistency between them). A-1 ICC shows total agreement between STV240 and ecgSTV but does not become significant between STV16 and the other two: STV16 overestimates ecgSTV (also STV240) as shown in the Bland-Altman plots in Figure 7 and the difference increases for high STV figures.

Figure 7. Bland-Altman plots: top ECGstv versus STV240, middle ECGstv versus STV16, bottom STV240 versus STV16.



5 CONCLUSIONS

STV16 is a well established algorithm evaluating short term variability. It has proven its effectiveness in adverse perinatal outcome recognition in predelivery assesment of fetal wellbeing but not during labour. Its design was empirically based on the basis of computational and storage capacity in the devices available at the time of its implementation and not on a pathophysiological basis such as fetal electrophysiological activity (Jones *et al*, 2022). Our work shows that the reference values for STV differ according to the algorithm used and this needs to be taken into account in its clinical application. STV240 shows a very close agreement with STV calculated from the fetal ECG signal but it is necessary to investigate whether this implies an advantage in identifying a state of fetal compromise.

Improving assisted interpretation in cardiotocography needs to explore new methods of computarized analysis and machine learning models (Aeberhard *et al*, 2023).

For that purpose, it is essential to have suitable records with raw signal/traces similar to those provided by the device developed. This will allow for an unbiased comparison of algorithms in order to identify those that best recognise scenarios of fetal distress.

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