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Software for computerised analysis of cardiotocographic traces

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ABSTRACT

Despite the widespread use of cardiotocography in foetal monitoring, the evaluation of foetal status suffers from a considerable inter and intra-observer variability. In order to overcome the main limitations of visual cardiotocographic assessment, computerised methods to analyse cardiotocographic recordings have been recently developed. In this study, a new software for automated analysis of foetal heart rate is presented. It allows an automatic procedure for measuring the most relevant parameters derivable from cardiotocographic traces. Simulated and real cardiotocographic traces were analysed to test software reliability. In artificial traces, we simulated a set number of events (accelerations, decelerations and contractions) to be recognised. In the case of real signals, instead, results of the computerised analysis were compared with the visual assessment performed by 18 expert clinicians and three performance indexes were computed to gain information about performances of the proposed software. The software showed preliminary performance we judged satisfactory in that the results matched completely the requirements, as proved by tests on artificial signals in which all simulated events were detected from the software. Performance indexes computed in comparison with obstetricians' evaluations are, on the contrary, not so satisfactory; in fact they led to obtain the following values of the statistical parameters: sensitivity equal to 93%, positive predictive value equal to 82% and accuracy equal to 77%. Very probably this arises from the high variability of trace annotation carried out by clinicians.

1. Introduction

At the end of pregnancy, assessing of foetal well-being depends on the evaluation of multiple parameters, many of them correlated to characteristics of foetal heart rate (FHR) signals recorded by means of Cardiotocography (CTG). This technique, widely used both in the antepartum and intrapartum period [1], consists of the simultaneous recording of FHR and uterine activity (generally referred as uterine contractions signal – UC) [2,3]. Both FHR and UC are simultaneously recorded and printed onto a paper strip. In the classical approach, clinicians, whose task is to classify the signal patterns, visually interpret this graphical representation. Many parameters of FHR signals need to be interpreted for the evaluation of foetal health status: the basal level of FHR signal

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(also called baseline), FHR variability (FHRV) and transient increases (accelerations) or decreases (decelerations) of the FHR. FHRV represents the beat-to-beat effect of foetal sympathetic and parasympathetic nervous systems and its changes may be also the result of the foetal sleep-wake cycle, drugs, umbilical cord compression, foetal hypoxia and such severe conditions as foetal acidemia [4]. Accelerations are the result of foetal movements and identify the foetal well-being, while decelerations are the symptom of foetal distress usually indicating the risk of foetal hypoxia [5], even if their interpretation is difficult and associated to different aspects such as shape, superimposed variability and delay with respect to UC [6].

Visual analysis of CTG recordings (sometimes here called CTG traces or only CTG) has a well-demonstrated poor reproducibility [7] due to the complexity of physiological phenomena affecting foetal heart rhythm [8] and being related to clinician's experience. A sufficiently high level of disagreement was noted between observers as well as for the same observer [9–11]. This great intra- and inter-observer variation negatively affects sensitivity and specificity in reading CTG traces [12]. Besides, abnormal patterns can be recorded both in case of foetal distress and in foetal well-being but during quiet periods of the foetus. Therefore, establishing foetal state is often a difficult issue in clinical practice and the erroneous evaluation of CTG may lead to unjustified invasive medical interventions. This is not just an ethical issue since in some countries CTG recording is a medical report with legal value [13–15].

In order to decrease the subjective nature of foetal state evaluation, the visual interpretation is more and more often replaced by automated computerised analysis, which has the theoretical advantage of providing a reproducible and objective interpretation of CTG traces and quantifying parameters that are difficult to assess by the human eye, such as short- and long-term variability [7,16]. Furthermore, it has been demonstrated that computerised CTG has also a great potential to improve the diagnosis of foetal asphyxia in labour [17]. Computerised systems are also able to provide an easily accessible means for storage, review and transmission of data and enhance the constitution of databases, with important clinical and research applications [7]. They have been developed since the late 1970s but the interest in this field is still alive since computerised CTG systems have not yet gained very wide clinical acceptance. This may be related to the limited demonstration of their validity and efficacy, as well as to the poor practicality of their routine clinical use [16]. At the same time, it is difficult to implement the heuristic rules used by clinicians during the diagnostic inference in signal processing algorithms [5]. Up to now, the basic idea in automatic CTG analysis has been the assessing of parameters historically and habitually used by clinicians for the diagnosis such as the baseline, followed by the detection of events like accelerations and decelerations, considering and measuring some morphological characteristics in the same way as the clinicians do by eye inspection [18]. Nevertheless, this is not a simple task; in particular, there is currently no consensus on how computer estimation of the FHR baseline should be performed [19], although the baseline is considered as one of the fundamental features of the FHR pattern because it can influence overall tracing interpretation and most of the other features rely on its estimation [20,21]. Besides, there is not still a unique criterion for defining accelerations, and analogous disagreement between authors can be found in establishing criteria for the detection of decelerations and contractions. Thus, developing a software that can be really helpful for clinicians in foetal monitoring represents a remarkable purpose.

The aim of this study is to present the main characteristics and potentiality of a new software for computerised analysis of antenatal CTG developed mainly for research purposes, which, although does not represent a diagnostic tool, can be also a useful technical support for clinicians. It has been the result of a research study of some previous automated systems for FHR analysis present in literature in order to join the estimation of the most relevant parameters for a more objective analysis. First target of the proposed computerised analysis system is to make automatic the procedure for measuring the parameters which are historically and still nowadays employed in daily clinical practice. Then, since many works highlight the usefulness of nonlinear techniques in the study of heart rhythm [22–25], other less traditional parameters are involved in order to enlarge information amount related to FHR.

2. Materials and methods

In this section an overall description of CTG recordings, software features and tests carried out is given; a more detailed analysis is reported in Appendix A. The software was completely developed in Matlab ver. R2011a. Concerning classical parameters, the implementation of the algorithm started from the indications by Mantel et al. [26,27], because they seem to be the most complete and detailed.

2.1. *Data set*

CTG traces here used to test software performances are part of a database which includes almost 400 signals recorded from 2000 to 2009 in clinical environment. All CTG were recorded during daily routine foetal monitoring in clinical environments from women between 31st and 41st week of gestation, both in antepartum and in intrapartum period; they last at least 20 min. The patients laid down in a rest position. Neonatal parameters such as Apgar score and new-born weight and other information such as eventual maternal pathologies had been also collected when available. Based on the available data, about 55% of pregnant women had a caesarean section and 35% a spontaneous delivery. In addition, 45% of births were male and 35% female.

Cardiotocographic signals were acquired using HP-135x or Sonicaid cardiotocographs equipped with an ultrasound Doppler probe to detect FHR signal and an external pressure transducer to record UC signal. In HP cardiotocographs, FHR and UC signals are internally stored at 4 Hz (corresponding to a sampling interval of 250 ms). On the contrary, in Sonicaid cardiotocographs, FHR and UC signals are unevenly stored.

Digital signals were acquired from the CTG devices to the computer's serial port via a standard computer cable, using a RS232 protocol. An interface (not described for sake of brevity)