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Research Article

Biosensors for Monitoring of Vital Functional Parameters during Medical Emergency

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Abstract. The objective of this work concerns the study of biosensors for monitoring of parameters and diagnosis of vital functional during first medical emergency. The study and analysis of vital parameters is extremely important in emergency medicine. The principle is based on the combination of the signals coming from the patient (vital functions), consists of measurement and comparison of the phase of active and reactive components of biologically active points (BAP) the transduction of such acquired signals and the processing of the obtained information. One of the advantages of reflex diagnostic methods is the fact that the response of BAPs to the change in the internal structure of the human body. These signals are proving instantaneous information on the functional state of 20 basic organ and system of the human body. The method will use one input variables (the classic physiological parameters and/or signals detected by using additive sensors) and one output variable which is correlated with the clinical condition of the patient. High information volume, accuracy, reliability, and reproducibility of data are supported in parallel in emergency diagnostics. A model will produce an association between the input variables and the output variable by using a data set established with the medical team. The proposed methodology improves standard systems such as reflex diagnostics, track and trigger and threshold (Early Warning Score). It is shown that good results for the prediction and early diagnosis in first medical emergency, through the adoption of the Fuzzy Set Theory.

Keywords: Biosensors, biologically active points (BAP), fuzzy logic, monitoring of medical parameters

1 Introduction

Therapy efficiency suffers greatly from limited in-vivo feedback. It is very difficult to obtain an objective picture of the processes occurring in living organisms, organs, tissues, and systems.

Today the study and analysis of vital parameters is extremely important in clinical medicine (Dias et al., 2018). There are various guidelines in "clinical practice" and the effort towards programming and developing of new clinical and scientific research is strong (Mok et al., 2015). It is worth noting that several solutions have been proposed for clinical methods and specific treatments (Burssens et al., 2016; Gueli et al., 2015; Mannino et al., 2011).

The evolution of the patient condition of first medicine emergency is essential in order to ensure early and rapid action in critical and/or traumatological patients that could have an immediate and/or progressive clinical deterioration (Kredo et al., 2016).

In fact, it should be noted that for patients with acute illness (Miller, 2016) (such as acute coronary syndrome, acute heart failure, arrhythmias, hyperkinetic, and hypokinetic disorder), a continuous vital signs monitoring is required (Khan et al., 2016; Mok et al., 2015).

Analysis of the Autonomous Nervous System through heart rate variability is important in health. Analysis of heart rate variability (HRV) is widely used as a standard method for assessing autonomic nervous functions. Alterations in parasympathetic and sympathetic nervous system activity result in beat-to-beat heart rate variation, and hence, this variation (heart rate variability [HRV]) reflects autonomic nervous system activity.

Heart rate variability by measuring the changes in the cardiac rhythm through time, is altered in pathological states, such as ischemic heart disease, and reduced variability is predictive of worse outcomes.

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Hence, the term Pulse Rate Variability (PRV) has been used to refer to HRV information obtained from pulse wave signals, such as the photoplethysmography (PPG).

Patients in emergency care are in fact subjected to a continuous control of the heart rate, blood pressure and, if necessary, they are supported with assisted artificial ventilation, mechanical cardiovascular support, and hemodialysis (Holden et al., 2002).

In order to ensure first medical assistant, it is particularly interesting to perform continuous monitoring and measurement of vital functions (physiological parameters) of the patient, including oxygen saturation, blood pressure, body temperature, respiratory rate, diuresis, and cognitive signals (consciousness state) (Paradiso et al., 2004).

Even more problematic is trying to precisely define the essence of functional disorders (pathologies). In human, besides the five widely known senses, there are three more known independent networks providing information about the functional state of group of organs, single organs, and different parts of organs: the skin, the outer ear or pinna, and the eye.

One possible approach for early detection in medical emergency, as reflex diagnostics.

This approach is based on measuring energetic characteristics of biologically active points (BAPs) (Burssens et al., 2016; Dias et al., 2018; Fratini et al., 2015; Gueli et al., 2015; Holden et al., 2002; Khan et al., 2016; Kredo et al., 2016; Mannino et al., 2011; Miller, 2016; Mok et al., 2015; Paradiso et al., 2004; Reddy et al., 2009). The advantage of reflex diagnostic methods is the fact that the response of BAPs to the change in the internal structure of the human body occurs prior to the clinical presentation of a disease. We do know that there are more than 3000 biologically active point (BAPs) connected (by meridians) and communicating with all organs and systems of the human body (Tabeeva, 1982).

Example, the BAPs pattern associated with an organ or system generates a specific link of certain components of the organism and is designed as meridian in traditional acupuncture.

Typically, such data can be obtained by using sensors and medical instrumentation, such as: the electrocardiograph, which provides the electrocardiogram (the data appear on a video terminal) (Fratini et al., 2015); a sensor that, connected to a patient's finger, is able to measure the level of oxygen in the blood (Reddy et al., 2009); a sensor that measures the level of carbon dioxide of the patient (Cuvelier et al., 2005); a catheter into the artery to continuously measure blood pressure (Krum et al., 2012); sensors for brain activity recording (EEG) (Curran et al., 2003); probe to measure the temperature (Houdas et al., 2013), etc...

However, it must be noted that the measure of a single vital sign does identify the clinical evolution and the state of the patient in first assistant medical emergency. For this reason, several solutions for the analysis of vital functions by using Early Warning Score (EWS) (Pedersen et al., 2018) have been proposed in literature.

The basic principle of this method is to collect physical parameters (easily to be measured through sensors) and building a score that allows a rapid evaluation of patient status. The numerical values obtained by using this approach provide an indication of the critical status by supporting and assisting the experience of the doctors, thus allowing the evaluation of the patient's condition. This approach is necessary to define the level of urgency indicating an alert condition and the type of clinical response. However, very often, it is interesting to detect thealterations preceding this stage, predicting critical condition for the patient. The work proposed in this paper is related with this context, in particular the study here conducted regards the phase before the observation study of medical intensive care patients. The basic idea concerns the acquisition of the signals coming from the patient (vital functions) during first medical emergency, the transduction of such acquired signals and the combination of the obtained information.

The proposed methodology is based on advanced mathematical techniques in order to study the signals with variable characteristics in the time domain, using standard systems such as "track and trigger", threshold (EWS) and including the use of the theory of fuzzy sets (Fuzzy Set Theory) (Asiain et al., 2018).

The basic principle is to collect the usual physiological parameters, which are easy to be acquired, and use such information as inputs of a mathematical model (fuzzy system) based on the theory of fuzzy sets and fuzzy logic. The system here proposed will use n input variables (the classic physiological parameters and/or signals detected by using additive sensors) and one output variable which is correlated with the clinical condition of the patient. The fuzzy model will produce an association between the input variables and the output variable by using a data set (rules) established with the medical team. The goal is to get a system capable to process the signals (physiological parameters) not only by using a binary logic (thresholds system), but also by using " if-then " rules. The proposed methodology will warn the medical team about condition of patient's deterioration (also in presence of a not dangerous/warning condition). These approaches will also give standardized results correlated with the evolution of the clinical status of the patient.

The proposed approach will optimize the medical alert, considering real case of emergencies, predicting acute degeneration conditions, such as cardiac arrest, improving the quality of life and health for all the involved people.

2 Method and Algorithm

One of the important tasks connected with generating decision-making rules is informative feature selection and selecting informative BAPs. The aforementioned features of "displaying" information include the transmission of a large volume of data (multiple diagnoses, symptoms, and syndromes) to one BAP. Due to the existing peculiarities of representing information about the condition of the human body on BAPs, various methods and algorithms have been suggested. These methods and algorithms are intended to search for special combinations of BAPs. The analysis of such combinations makes it possible to confirm the diagnosis in question or to refute the diagnosis reflected in BAPs according to reference data when the disease has not affected a person. The combinations described above are called "diagnostically important points" (DIPs) [5]. Special research on prediction, early and differential diagnostics of cardiovascular system damages, of the digestive tract, nervous system, musculoskeletal system, of the respiratory system, etc. has shown that the use of DIPs, in combination with other informative features, enables us to obtain decision rules providing high-quality classification.

According to the recommendations for generating decision rules it is reasonable to apply decision-making based on Early warning scores (EWSs) and Fuzzy Logic (Klir et al., 1997; Korenevsky et al., 2008; L., 1996).

2.1 Working principle

Early warning scores (EWSs) are extensively used to identify patients at risk of deterioration in hospital (Asiain et al., 2018; Pedersen et al., 2018). It is worth noting that this method, and several similar approaches, can support clinical decision-making around escalation of care and can provide a clear means of communicating clinical acuity between clinicians and across different healthcare organizations. EWS systems are based on five measurements of physiological parameters normally performed, as shown in table 1: respiratory rate, oxygen saturation, body temperature, systolic blood pressure, pulse rate, with the addition of the level of consciousness.

The last parameter will not be considered in the developed algorithm. Each parameter is graduated in levels, and a numerical value is assigned to each of them.

The sum of the numerical values provides the measure of the deviation from the normal physiology. As it is shown in table 2 the establishes three levels of clinical alert can be summarized as[1]:

- Low: score from 1 to 4;
- Medium: score from 5 to 6, or a score of 3 for a single parameter;
- High: score 7.

Depending on the score obtained, the patient's monitoring frequency is determined. As already mentioned, the classic EWS method is often not able to detect physiological degeneration caused by slow alterations of vital parameters. This is because this method is based on threshold criteria.

2.2 Algorithm

Fuzzy logic is a computing technique that is based on the degree of truth. A fuzzy logicsystem uses the input's degree of truth and linguistic variables to produce a certain output. The state of this input determines the nature of the output. The fuzzy logic allows to associate weights of belonging through the so-called membership functions, that admit values between 0 and 1, unlike Boolean logic which admits only the two above mentioned values.

This helps to create rules that are very similar to human language, by moving away from the purely mathematical one.

It is therefore necessary, as a first step, to create membership functions for each physiological parameter.

The fuzzy system has been implemented through the Fuzzy System Designer included in LabVIEW environment.

Five membership functions, three of them with triangular shape and the other two (the external ones) with trapezoidal shape.

RR1 and RR5, in fact, represent the critical values to which, in the table 1, a score of three is associated.

On the vertical axis the membership grades 1 in the range 0–1 are reported. The output variables are instead represented only by triangular functions. In order to recall the aggregate scores described in table 1, the functions are defined within the range 0–7.

Once the functions have been created for all the physiological parameters, they need to be correlated with each other by means of the if-then rules. Let us call p the number of physiological parameters and f the number of functions for each of them. The number of rules r is given by

$r = p^f$

Since, in this case, for each vital parameter several function equal to five has been chosen, the total number of rules is equal to 3.125. As the implementation of such a high number of rules involves a considerable burden,

[1] https://www.weahsn.net/wp-content/uploads/NEWS_toolkit_njd_19Apr2016.pdf.

Score	3	2	1	0	1	2	3
Systolic BP	⩽70	71–80	**81–100**	101–199	-	⩾200	-
Heart rate (HR)	-	⩽40	41–50	51–100	101–110	**111-129**	⩾130
Respiratory rate (RR)	-	⩽8	-	9–14	**15–20**	21–29	⩾30
Temperature (°C)	-	34.9	-	**35.0–38.4**	-	⩾38.5	-

Table 1: The EWS Scoring System.

NEW SCORE	Clinical risk	Response
Aggregate score 0–4	Low	Ward-based response
Red score Score of 3 in any individual para	Low-medium	Urgent ward-based response
Aggregate score 5–6	Medium	Key-threshold for urgent response
Aggregate score 7 or more	High	Urgent or emergency response

Low: score from 1 to 4;
Medium: score from 5 to 6, or a score of 3 for a single parameter.
High: score 7.

Table 2: EWS aggregate scores and responses.

whether at the debug or testing stage, a coupling of up to two physiological parameters at a time was preferred.

According to the opinion of a medical team, following their clinical observation method, the couplings are as follows:

- Systolic blood pressure + Pulse;
- Oxygen saturation + Respiration rate.

Since the temperature is the last parameter to be taken into consideration, it will be coupled with both results of the above said couplings. The final score will be the maximum value between the results coming from the temperature and the previous coupling combination. This method allows to considerably reduce the number of rules without neglecting the desired correlations. The whole algorithm is synthetized in figure 2.

A rule is a relationship between input and output variables. It will take the following syntax:

If Oxygen Saturation is Sp3 and Respiration rate is RR2 THEN R2 is 5

The defuzzification method used to convert the output variables into crisp numerical values is the Center of Area, which calculates the centroid under the weighted sum of the results. This method is the best trade-off between multiple output linguistic terms.

To evaluate the algorithm, a Graphical User Interface in LabVIEW environment has been developed. As it is shown in figure 3, on the left panel it is possible either to set the values for each physiological parameter manually or get them through a data acquisition (DAQ- 6009) board. Moreover, numerical indicators reporting the partial score obtained from the above-described couplings can be found. On the right panel, instead, the scores obtained from the standard and the fuzzy methods are compared.

The system was tested by setting a set of some vital parameters as shown in table 3. In the first row we can observe an alteration of three parameters, namely respiration rate, pressure, and pulse. In this case, the standard EWS method produced a score of 2, differently from the fuzzy method which produced a score equal to 4. Increasing the temperature by 2°C both methods indicate an increase in the score by one point.

In the third and fourth row, instead, the predictivity of the algorithm is appreciated. In the two cases an alteration of oxygen saturation along with a high pulse can be observed. In the first case the traditional method indicates a score of 3, while the fuzzy one gives the score of 4. When increasing the pulse rate, the traditional method does not vary; conversely, with the fuzzy method a clinical degeneration shifting from a score of 4 to a score of five can be noticed.

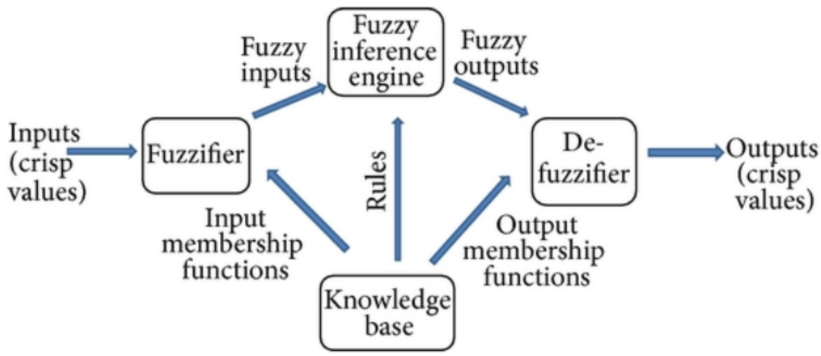

Figure 1: Fuzzy logic.

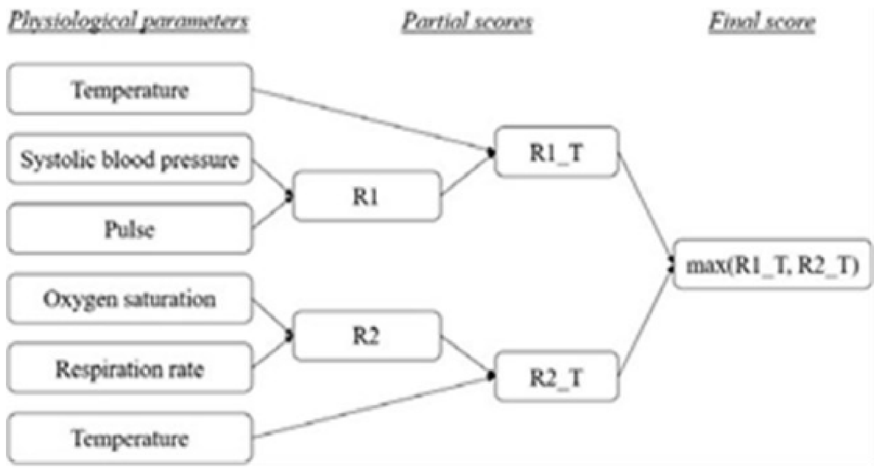

Figure 2: Synthetic scheme of the algorithm.

Parameters					**Score**	
Respiration rate	SpO_2	Pressure	Pulse	Temperature	Traditional	Fuzzy
20	100	150	124	36.5	2	4
20	100	150	124	38.5	3	5
12	94	130	124	36.5	3	4
12	94	130	126	36.5	3	5
21	97	200	70	37.5	2	4

Table 3: A comparison between the EWS traditional EWS score and the Fuzzy score.

3 Conclusion

In this paper biosensors for the estimation of medical precursors have been presented including the model and the implementation through a LabVIEW routine. It is worth noting that the proposed solution improves standard systems such as "track and trigger", heart rate variability response during stressful event and EWS through the adoption of the Fuzzy Set Theory in order to produce an association between the input variables and the output variable by using a data set established with the medical emergency team. The work will be do with a more exhaustive study based on transducers able to measure the physiological parameters of interest in the perspective to perform a clinical validation of the proposed method.

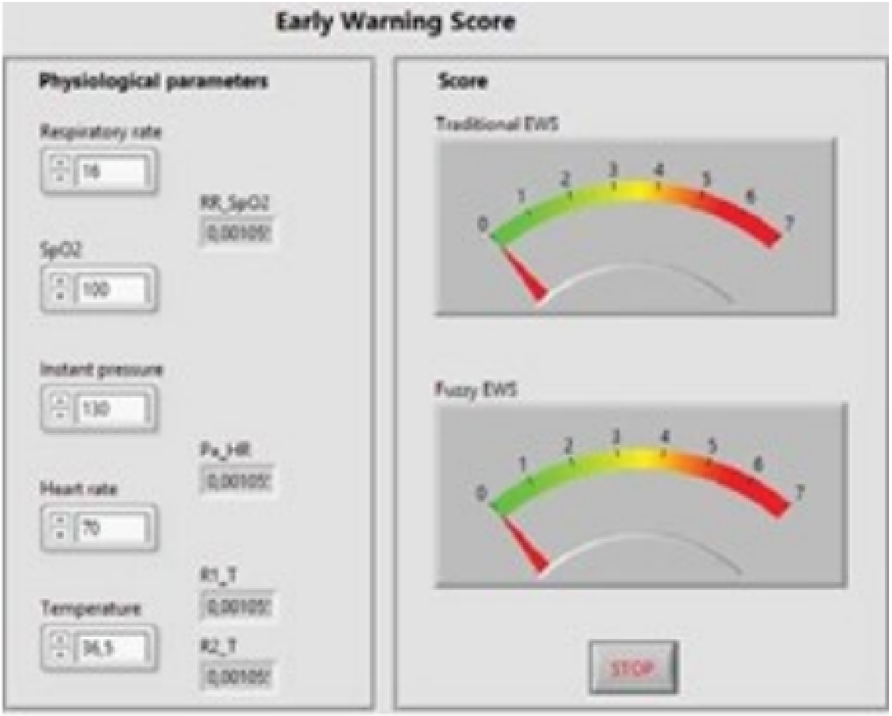

Figure 3: Implementation of the biosensors for the valuation of medical parameters: a) Labview routine, b) front panel with aggregate scores and responses

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