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ANAESTHESIA MONITORING USING FUZZY LOGIC

Mirza Mansoor Baig, ME[1], Hamid GholamHosseini, PhD[1], Abbas Kouzani, PhD[2] and Michael J. Harrison, MD[3]

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ABSTRACT. Objective. Humans have a limited ability to accurately and continuously analyse large amount of data. In recent times, there has been a rapid growth in patient monitoring and medical data analysis using smart monitoring systems. Fuzzy logic-based expert systems, which can mimic human thought processes in complex circumstances, have indicated potential to improve clinicians' performance and accurately execute repetitive tasks to which humans are ill-suited. The main goal of this study is to develop a clinically useful diagnostic alarm system based on fuzzy logic for detecting critical events during anaesthesia administration. **Method.** The proposed diagnostic alarm system called fuzzy logic monitoring system (FLMS) is presented. New diagnostic rules and membership functions (MFs) are developed. In addition, fuzzy inference system (FIS), adaptive neuro fuzzy inference system (ANFIS), and clustering techniques are explored for developing the FLMS' diagnostic modules. The performance of FLMS which is based on fuzzy logic expert diagnostic systems is validated through a series of off-line tests. The training and testing data set are selected randomly from 30 sets of patients' data. **Results.** The accuracy of diagnoses generated by the FLMS was validated by comparing the diagnostic information with the one provided by an anaesthetist for each patient. Kappa-analysis was used for measuring the level of agreement between the anaesthetist's and FLMS's diagnoses. When detecting hypovolaemia, a substantial level of agreement was observed between FLMS and the human expert (the anaesthetist) during surgical procedures. **Conclusion.** The diagnostic alarm system FLMS demonstrated that evidence-based expert diagnostic systems can diagnose hypovolaemia, with a substantial degree of accuracy, in anaesthetized patients and could be useful in delivering decision support to anaesthetists.

KEY WORDS. patient monitoring systems, fuzzy logic, anaesthesia monitoring, hypovolaemia diagnosis, ANFIS.

INTRODUCTION

Over the past two decades, computers have played an important part in research related to clinical decision-making process. Over the next two decades, computers would be capable of delivering significant assistance to healthcare professionals and patient monitoring. In the 1960's, Szolovits et al. [1] and Shortliffe et al. [2] suggested a coherent summary of computer-aided decision making in medicine. Anaesthetists are typically required to monitor displays over extended periods, and to execute overt detection responses to the appearance of low probability critical signals. Although signals are usually perceivable to the alerted observers, there is still possibility of being

From the [1]School of Engineering, Auckland University of Technology, Private Bag 92006, Auckland 1142, New Zealand; [2]School of Engineering, Deakin University, Geelong, VIC 3217, Australia; [3]Department of Anaesthesia, Wellington Regional Hospital, Wellington, New Zealand.

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Address correspondence to H. GholamHosseini, School of Engineering, Auckland University of Technology, Private Bag 92006, Auckland 1142, New Zealand.
E-mail: hgholamh@aut.ac.nz

missed in the operating environment [3]. Hence, expert systems have the potential to improve clinicians' performance by accurately executing repetitive tasks for which humans are ill-suited, such as physiological parameter analysis and surveillance. Additionally, expert systems can be employed to standardize clinical guidelines and deliver assistance to the clinicians [4, 5]. Human errors in anaesthesia account for more than 80% of the preventable mishaps [6]. Computers have the capability to monitor large volumes of diverse data rapidly, whereas humans are only able to monitor a maximum of seven different parameters at a time [7]. Van den Eijkel et al. [8] suggested that such limitations could be overcome by using a knowledge-based anaesthesia monitor (expert system) which is an evidence/knowledge-based system that analyses the data and presents the results to the anaesthetist; this could potentially prevent such mishaps.

Decision support systems in anaesthesia monitoring

Decision Support Systems (DSS) are designed to integrate information from a patient monitoring system, which is computerised medical knowledge base, and an inference engine to generate case-specific and situation-specific advices [9, 10]. The DSS could also help anaesthetists to make decisions in complex situations where continuous monitoring of highly critical physiological parameters such as heart rate (HR), blood pressure (BP), end-tidal carbon-dioxide ($ETCO_2$) and systolic arterial pressure (SAP) require immediate response [11].

The challenge is to develop a computer application that would be able to accumulate all information in a variable, or several variables, over time, and identify when the trend in observations has changed. In recent years, there has been rapid growth in patient monitoring approach using DSS, smart alarm monitoring systems, expert systems, computer-aided protocols and fuzzy logic systems [4, 12–15].

Background review

Computer programs employing fuzzy logic are intended to imitate human thought processes in complex circumstances, but to function at greater speed [16]. Fuzzy logic-based expert systems have been developed in many areas of patient monitoring. Investigation towards control of anaesthetic gases and BP by Sieber et al. [17] indicated that accurate control of mean alveolar concentration of isoflurane can be performed by a system that altered the gas flow rates. Carregal et al. [18] reported that postoperative pain control resulting in the patient's target analgesia level achieved a positive result as much as 77% of the time, and there are many more such examples [19].

Fuzzy logic based systems

Lowe [20] developed a system called SENTINEL which could identify faults and assist clinicians in diagnosing of anaesthetic patients. It detects pathological events during anaesthesia by on-line analysing physiological signals. Moreover, fuzzy pattern matching technique which is known as fuzzy trend templates was employed to detect vaguely specified patterns in multiple physiological data streams. As an expert system, SENTINEL incorporated the knowledge of many consultant anaesthetists and achieved sensitivity and specificity accuracy of above 90% in the diagnosis of seven common or serious conditions that can arise during anaesthesia.

Lowe and Harrison [21] developed a fuzzy logic based algorithm for detecting a rare pathological condition called malignant hyperpyrexia (MH). In this study, rule-based diagnoses were performed to detect the changes in the patterns of symptoms. In an offline validation of the algorithm, the system detected MH 9 min before the anaesthetist. These investigations demonstrate how expert systems can be employed to facilitate and enhance anaesthetists' performance in the clinical environment, thus improving patient safety.

Esmaeili et al. [22] designed a fuzzy rule based system which integrates main features of an electroencephalogram (EEG) to quantitatively estimate the depth of anaesthesia (DoA). The experimental data was divided into four well-defined anaesthetic states: awake, moderate anaesthesia, surgical anaesthesia, and isoelectric (deeply unconscious). Statistical analysis of the selected EEG features was used to design the membership functions (MFs) of the fuzzy logic system. Training data was employed in an adaptive network-based fuzzy inference system (ANFIS) to classify partitions based on the level of DoA. Moreover, a fuzzy inference system (FIS) and designed output MFs were employed to extract efficient fuzzy IF–THEN rules for this system. The fuzzy rule-base index (FRI) was used to calibrate the rules between 0 (isoelectric) and 100 (fully awake). The main focus of the study was to simplify the mutual knowledge exchange between the human expert and the machine, and achieve enhancement in both the interpretability of the results and the performance of the system.

Mahfouf et al. [19] developed a Mamdani type of fuzzy model using anaesthetists' knowledge described by fuzzy IF–THEN rules. Clinical data was used to construct the patient model. An ANFIS was then used to train fuzzy Takagi–Sugeno–Kang (TSK) models so as to describe different signals. A stimulus model was used to establish the effects of surgical stimulus on HR and SAP according to the level of analgesia used to model different signals.

Harrison and Connor [23] developed an anaesthesia alarm system that detects the changes in SAP and states that a decrease in SAP of 10 mmHg from a previous value of 70 mmHg has a greater clinical significance than a decrease of 10 mmHg from 150 mmHg. They processed SAP data to create a mathematically straight forward statistical tool for sampling intervals up to 5 min. Using Pythagoras's theorem, they combined the value for the standard deviation of SAP and the standard deviation of the change in SAP, so instead of alarms being set in mmHg, they would be set in standard deviations. This technique was developed further using principal component analysis to isolate uncommon deviations from normal, clinically unimportant, physiological variations. This may turn out to be clinically useful.

Otero et al. [24] developed a multivariable fuzzy temporal profile (MFTP) model, a formal model for describing certain monitoring criteria as a set of morphologies defined over the temporal evolution of the patient's physiological variables and a set of relations between them. The MFTP model represents these morphologies through a network of fuzzy constraints and a knowledge acquisition tool, TRACE, with which clinical staff can design and edit alarms based on the MFTP model. Results show that sixteen alarms were designed using 196 h (78 patients) of data in which among 912 triggered alarms only 7% were false positives.

Belal et al. [25] developed an open loop feedback intelligent system for neonatal intensive care management. The system collects 18 parameters from the bedside monitor and ventilator using a medical information bus (MIB) system. The validation process compared the recommendations triggered by the system with the user feedback (agree, disagree, wait). The clinician agreed with 91% of the system's ventilation decisions, 94% of oxygenation decisions. The overall percentage of the agreement between the system and the clinician was 93%.

Most of the reviewed expert systems demonstrated a significant improvement in the diagnosis systems which can facilitate practitioners' performances in the clinical environment. However, using only off-line data with a set of conditions may cause some degradation and errors in these systems for on-line applications. Furthermore, due to their broad-spectrum applications, these systems may generate lots of false alarms when dealing with a specific pathological event such as hypovolaemia. In addition, some of these methods suffer from lack of user-friendly display which is normally requested by clinicians. The display modules of the reviewed systems are designed to encompass the broader case scenarios which require more complexity.

That is, the objective of the current research is to improve the previously designed systems. The proposed FLMS is evaluated both with off-line and on-line data collected from 30 patients during surgery. It can be realized by a user-friendly display for a specific clinical event, such as hypovolaemia, and it can reduce the number of false alarms significantly. Moreover, it is aimed to reduce the system complexity by imposing limited number of rules specifically related to hypovolaemia. For example, seven fuzzy rules are introduced to not only detect the on-set of hypovolaemia but also classify this event as severe, moderate, and mild.

Hypovolaemia

Hypovolaemia refers to a surgical condition in which rapid fluid loss results in multiple organ failure due to decrease in volume of blood plasma. Harrison and Connor [26] have described the heuristic relationships patterns for some common critical states which might arise during anaesthesia administration (hypovolaemia). These heuristic relationships (refer Table 1) combine the transformation in observable physiological variables like BP, HR and pulse volume (PV) to reveal the patterns for clinical pathological states. For instance the heuristic relationship for absolute hypovolaemia is identified by an increase in HR and decrease in BP and decrease in PV. The following sections give an insight to the development stages of the proposed FLMS system which include data collection, data conversion, design and structure of the proposed system.

FUZZY LOGIC MONITORING SYSTEM DEVELOPMENT

Fuzzy logic is generally an effective tool for describing the characteristics of a system that is complex or too difficult to be defined by a precise mathematical analysis. The theory behind fuzzy logic is based on approximate reasoning which plays a major role in the human thought process. The aim of fuzzy logic is to build a flexible information processing system which provides soft decision strategy resembling human decision making. It delivers a remarkably simple way to draw definite conclusions from vague, ambiguous, or imprecise information. In a sense, it resembles human decision making with its ability to work with approximate data yet find precise solutions [27]. In the following section the experimental data used to develop and evaluate the proposed fuzzy logic based system is explained.

Table 1. The limits of normalized parameters for mild, moderate and severe Hypovolaemia

Hypovolaemia	Mild	Moderate	Severe
Heart rate (HR)	1.75–3	3–5	5 & >
Blood pressure (BP)	2.75–5	5–6	6 & >
Pulse volume (PV)	4–6	6–8	8 & >

Data collection and data conversion

The physiological data was downloaded from the S/5 Datex-Ohmeda (GE, Datex-Ohmeda, Helsinki, Finland) anaesthesia monitor for patients undergoing major surgery. The data was collated with informed consent from 30 patients in the Auckland City Hospital operating theatre suite in New Zealand, with the respective local ethical approvals obtained. A software program called "S/5 Collect from GE Healthcare Ltd." was employed for data acquisition.

However, the S/5 Collect software application can only collect data from S/5 monitor and download it into the data collection computer. The data has then to be saved into a digital data file, in DOF format, which can be used for offline analysis. There is no provision for relaying data to any other device or application. Therefore, it cannot be used for real time data collection and testing. The data collection methodology had to be changed when the hospital's anaesthesia data logging system (IDAS; SaferSleep Ltd) was introduced which occupied the only available serial port. Part of the collated data using S/5 Collect, was utilized for offline testing of this project as indicated in the setup shown in Figure 1.

DOMonitor.Net [28] is a JAVA.NET-based data collection application. Originally, it was used to acquire data from the S/5 monitor, save captured data to a digital file, and simultaneously relay the data over another serial port. The digital file saved by the application can be used for offline analysis. DOMonitor had to be modified so that the acquired data could be relayed for real-time analysis. This application served as a very handy tool for testing as it performed the tasks simultaneously; this streamlined the whole process. It acquires data from the S/5 monitor and relays it to IDAS over another serial port, and also transmits the required signals over a transmission control protocol (TCP) port. It saves the selected waveform data to a readable digital file that can be accessed in offline mode for retrospective analysis.

Design and structure of the proposed FLMS

Figure 2 shows the building blocks of the proposed FLMS; it consists of the following nine sections:

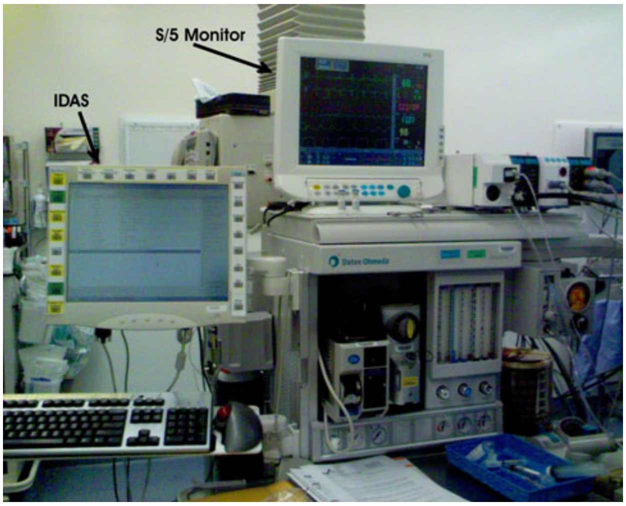

Fig. 1. Operating theatre setup with Datex S/5 monitor and IDAS system.

1. Raw Data—The input patient data which contains noise.
2. Filtering—A combination of lowpass, highpass and variance based filters applied to the raw data for smoothing/filtering purposes.
3. Filtered Data—The filter output used by the FLMS for analysis and diagnosis purposes.
4. Clustering—Clustering of numerical data forms the basis of many classification and system modelling algorithms. The purpose of clustering is to identify natural grouping of data from a large data set to produce a concise representation of a system's behaviour. Matlab's fuzzy logic toolbox allows finding the clusters in the input–output training data (patients' training data). Two types of clustering techniques can be adopted, subtractive and fuzzy c-means (FCM) clustering. The clustering

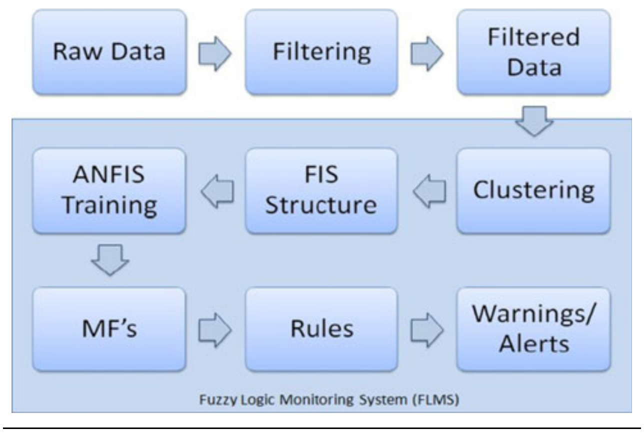

Fig. 2. Building blocks of the proposed FLMS.

stage of the proposed system employs FCM algorithm to provide information about the cluster centres as well as assigning membership grades for each cluster.

5. Fuzzy inference system (FIS)—Using the clustered information obtained in the previous section, a Sugeno-type FIS structure was created for training the data through an ANFIS.
6. Adaptive neuro-fuzzy inference system (ANFIS)—An ANFIS was used to train fuzzy model for the classification of the patient data. Sugeno model is used for training and testing of the ANFIS and Mamdani model is used for testing of the FLMS.
7. Membership functions (MFs)—The selection of the MF's limits, which is one of the important part of the system, was set after analysing the clustered data and ANFIS outputs. Three membership functions were set for each input as mild, moderate, and severe to generate a total of nine (3×3) MFs for three inputs of HR, BP and PV. Mild, moderate and severe refer to different degrees of abnormally high values of these parameters. The limits and range values of each MFs were set accordingly to map the corresponding input to the desired output space.
8. Rules—The rules were created using all nine MFs to map the best output to each input and include all possible levels of hypovolaemia which were detected throughout the training sessions. The rules partition themselves according to the fuzzy qualities associated with each clusters.
9. Warning/Alert—The FLMS generates warnings or alerts as an output when the hypovolaemia level is mild, moderate, or severe.

The following section explains the details of the proposed FLMS with three conditions and seven rules.

The FLMS flowchart

The filtered data was divided into 5-min intervals and used as batches in the FLMS for testing. For some patients the 5-min interval was increased to 10 or 15 min, depending on the data quality. Figure 3 shows the FLMS flowchart imposing the following three main conditions:

1. *Three inputs:* The system checks for the detection of HR, BP and PV as the acceptable inputs.
2. *3 × 3 MFs:* As discussed in the previous section a total of nine MFs were set for HR, BP and PV parameters. Any value below the mild would be considered as normal.
3. *Seven Rules:* The rules were set using the training data set with their MFs. Sugino type of fuzzy model was selected considering anaesthetists' knowledge as described by fuzzy IF–THEN rules and the training data set were used to construct the rules and patient model as follows.

I. If (ECG-HR is mild) and (BP is mild) and (PV is mild) then (HYPOVOLAEMIA is mild).
II. If (ECG-HR is moderate) and (BP is moderate) and (PV is moderate) then (HYPOVOLAEMIA is moderate).
III. If (ECG-HR is severe) and (BP is severe) and (PV is severe) then (HYPOVOLAEMIA is severe).
IV. If (ECG-HR is mild) and (BP is mild) and (PV is moderate) then (HYPOVOLAEMIA is moderate).
V. If (ECG-HR is mild) and (BP is moderate) then (HYPOVOLAEMIA is mild).
VI. If (ECG-HR is mild) and (BP is mild) and (PV is severe) then (HYPOVOLAEMIA is moderate).
VII. If (ECG-HR is mild) and (BP is severe) and (PV is moderate) then (HYPOVOLAEMIA is moderate).

While it is possible to use more rules than the above-mentioned seven rules, it was found that adding more rules will increase the number of false alarms (false positives and false negative). If all three conditions that are related to inputs, MFs and rules become true and that at least one of the seven rules is satisfied, then the system

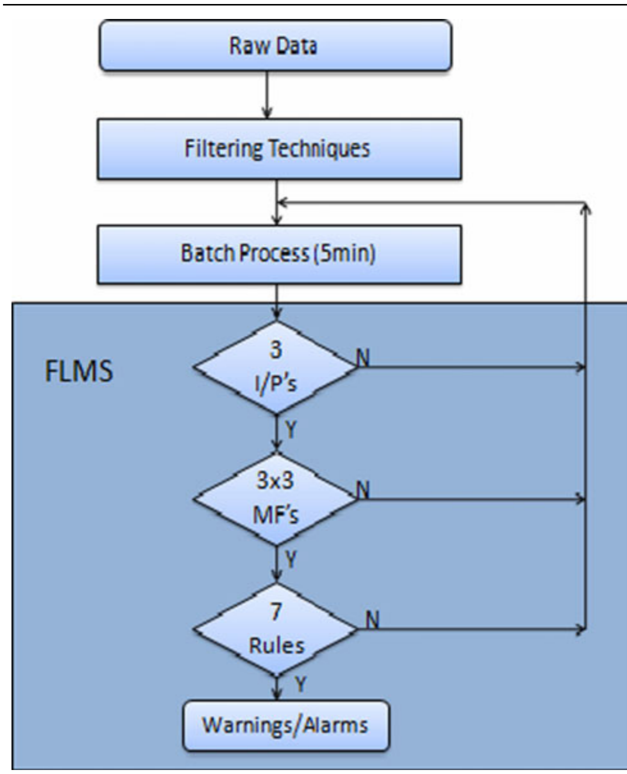

Fig. 3. Flow chart of the proposed FLMS.

generates a warning according to the level of Hypovolaemia. Otherwise, a normal situation is inferred.

Next section presents details of the FLMS's diagnosis features and the criteria used to obtain the critical values for detecting changes in the parameters.

Diagnosis features of the proposed FLMS

The filtered data used for offline simulation and analysed retrospectively by revisiting all available patient information for each record. The FLMS can be used in real-time with some modifications in the data analysis to overcome any possible delay in diagnosis of Hypovolaemia. The data from 30 patients were divided into sub intervals of 5 min, and every three intervals were re-combined to a 15-min time slot. Epochs of 15-min durations were used for offline analysis to match the anaesthetist's diagnosis which is made at 15-min intervals.

The FLMS's offline version is capable of reading the given patient data files. It can analyse data and generate alarms for the complete data set obtained from the patient files. The output of the FLMS has been classified into three categories: mild, moderate, and severe based on the following limits and conditions:

- The limits of MFs were set so that the system can detect changes in the input parameters, rather than the crisp numerical values.
- The mean-removed values of each 5-min time interval data (HR, BP and PV) were calculated. The standard deviation (SD) of each parameter (HR, BP and PV) for the whole data set was also calculated.
- The normalization of each parameter for every 5-min interval was performed by dividing the mean-removed data by its SD. For example, the normalized HR for every 5-min interval was calculated by dividing the mean-removed values by the SD of the whole HR data.

$$|\text{HR value} - \text{mean HR value}|/\text{SD}$$

- The normalised value was used to obtain the changes in parameters rather than the crisp numerical values. The limits of each normalised parameter for mild, moderate and severe hypovolaemia are indicated in Table 1. For example if the normalised HR is greater than five and the normalised BP is greater than six and the normalised PV is greater than eight then the hypovolaemia is severe.
- Normal conditions for the system will be when the normalised HR is less than 1.75, the normalised BP is less than 2.75 and the normalised PV is less than four.

Following section discusses the validation of results of the proposed FLMS using kappa analysis and comparing the results with other monitoring systems.

VALIDATION AND TESTING

Diagnostic speed and accuracy may vary between anaesthetists, the authenticity of the diagnosis depending on their skills and experience. For evaluating the diagnostic performance of the FLMS, Kappa analysis [29] was used to measure the level of agreement its diagnosis with the one presented by an expert anaesthetist. Kappa is used as the measure of how accurately FLMS can mimic anaesthetists' performance. The value of Kappa presented in Table 2 indicates the level of agreement/disagreement between the expert and FLMS.

The diagnostic performance of FLMS was verified through a series of offline (retrospective) trials using the data from 30 patients in a simulation environment. Real-time trials are required to complete the validation and fine-tuning of the system.

FLMS was trained with data from 15 patients and tested with data from the remaining 15 patients each with 15-min epochs. The training and testing data sets were selected randomly form the whole 30 sets of patient's data. Table 2 summarizes the Kappa analysis results for FLMS's performance and compare it with RT-SAAM. In this table, P_o, P_{pos}, and P_{neg} are overall, positive, and negative agreements, respectively. SE represents the standard error and $CI_{95\%}$ is 95% confidence intervals for Kappa.

The results show that the developed diagnostic system (FLMS) is capable of diagnosing the pathological events with a substantial level of agreement with the anaesthetist. The level of disagreement needs further analysis as it is possible that FLMS was correct and the anaesthetist was wrong.

Table 2. Comparing Kappa results of FLMS and RT-SAAM [30]

System	Overall Agreement P_o	Positive Agreement P_{pos}	Negative Agreement P_{neg}	Agreement by Chance P_e	Standard Error SE	95% Confidence Intervals for K $CI_{95\%}$	Kappa Value K
FLMS	0.89	0.80	0.92	0.59	0.06	0.85 and 0.61	0.73
RT-SAAM [30]	0.81	0.83	0.79	0.50	0.06	0.73 and 0.51	0.62

Table 3. Summary of six fuzzy-based systems and the proposed FLMS

Study	Technique/method used	Parameters used	Diagnostic events	Study results
Lowe [20]	SENTINEL monitoring system, that helps in FDD	HR, SAP, MAP, ETCO2, RR, BP, PV, SPO2	Seven different physiological events	Sensitivity and specificity above 90%
Lowe and Harrison [21]	Fuzzy logic based algorithm	SBP, HR, ETCO2	Malignant hyperpyrexia (MH)	Detected MH 9 min before the anaesthetist's diagnosis
Belal et al. [25]	An open loop feedback intelligent system	18 parameters	Ventilation and oxygenation management system	Clinician agreed with system's ventilation of 91% and oxygenation of 93%
Otero et al. [24]	A multivariable fuzzy temporal profile model	HR, BP, RR, SpO2	Addressing the flaws and limitations of threshold alarms	Out of 912 alarm triggered, only 7% were false positives
Harrison and Connor [23]	An anaesthesia alarm system based on principal component analysis	SAP	Detects the changes in SAP	The system output is more clinically useful
Bhupendra et al. [30]	RT-SAAM using fuzzy, probabilistic and SPV modules	HR, SAP, MAP, ETCO2, RR, BP, PV	Two physiological events	Substantial to fair level (K = 0.62) of agreement with anaesthetist
FLMS	Fuzzy rule based system, FIS, ANFIS	BP, HR and PV	Detection of Hypovolaemia	Substantial to fair level (K = 0.73) of agreement with anaesthetist

Table 2 also compares the Kappa analysis results for the proposed system and RT-SAAM. The Kappa value of FLMS and RT-SAAM is 73 and 62%, respectively. It shows a significant improvement in the performance of the proposed FLMS and a higher level of agreement with the anaesthetist in comparison with the previously developed RT-SAAM [30].

Table 3 summarizes the methods, parameters used, diagnostic events, and the results of six fuzzy-based expert systems as reviewed in the introduction [20, 21, 23–25, 30] with the ones for the developed diagnostic system (FLMS). The results demonstrate a significant improvement in the proposed system particularly in terms of the level of agreement with anaesthetist in diagnosing the on-set of hypovolaemia as well as classifying its level to severe, moderate, and mild.

Moreover, the FLMS performance in relation to the computational power and the execution time is superior in comparison with some of the existing systems employed for fault detection and diagnosis in anaesthesia [20]. The FLMS was trialed with 15 patients' data with the average duration of 5 h. In total the system was trialed with approximately 75 h data. Training time for the FLMS was approximately 10 s and the testing time was approximately 5 s for each patient's data set. The following section discusses the result achieved by the system with some recommendations in order to make the system more clinically useful in future.

DISCUSSION

The proposed FLMS system achieved the overall agreement of 89% with anaesthetist in offline mode. The FLMS has been developed using three MFs and seven rules to diagnose hypovolaemia through detecting changes in the physiological parameters with respect to their SD limits. It is expected that the proposed optimally designed alarm system generates warning within a short interval in order to provide the opportunity for clinicians to take appropriate action before a critical pathological event occurs. On the other hand, the system should limit its false alarms. To fulfil these criteria, the system needs to detect trends as well as monitor thresholds in order to alert anaesthetists before the dependent variable reaches a critical level. Several trend detecting alarm systems have been designed to deactivate the alarms if the adverse condition persists. Moreover, including more input parameters would improve online detection of other anaesthesia related events.

The FLMS was trialled with offline data using 30 patients data divided into sub-intervals of 5 min for each record. In comparison with the anaesthetists who normally check the Hyphovolaemia every 15 min, the allocated 5-min delay in triggering the FLMS alarm was found to be acceptable. However, as a future work it would be possible to consider the overlapping windows for patient's data to achieve a faster response.

CONCLUSION

The developed diagnostic alarm system has indicated that evidence based expert diagnostic systems can accurately diagnose hypovolaemic events in anaesthetized patients and can be useful in delivering of decision support to the anaesthetists. The complete validation of the system, as a clinically useful diagnostic alarm system, can only be verified after real-time trial. This system is ready to be tested in the real-time setup, although it is likely that it will need further refinement and enhancement with additional features for routine clinical use. This system can be considered as a clinically useful tool as verified by the overall results, and when compared with other monitoring systems.

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