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Improving the anesthetic process by a fuzzy rule based medical decision system

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ABSTRACT

Objective: The main objective of this research is the design and implementation of a new fuzzy logic tool for automatic drug delivery in patients undergoing general anesthesia. The aim is to adjust the drug dose to the real patient needs using heuristic knowledge provided by clinicians. A two-level computer decision system is proposed. The idea is to release the clinician from routine tasks so that he can focus on other variables of the patient.
Methods: The controller uses the Bispectral Index (BIS) to assess the hypnotic state of the patient. Fuzzy controller was included in a closed-loop system to reach the BIS target and reject disturbances. BIS was measured using a BIS VISTA monitor, a device capable of calculating the hypnosis level of the patient through EEG information. An infusion pump with propofol 1% is used to supply the drug to the patient. The inputs to the fuzzy inference system are BIS error and BIS rate. The output is infusion rate increment. The mapping of the input information and the appropriate output is given by a rule-base based on knowledge of clinicians.
Results: To evaluate the performance of the fuzzy closed-loop system proposed, an observational study was carried out. Eighty one patients scheduled for ambulatory surgery were randomly distributed in 2 groups: one group using a fuzzy logic based closed-loop system (FCL) to automate the administration of propofol (42 cases); the second group using manual delivering of the drug (39 cases). In both groups, the BIS target was 50.
Conclusions: The FCL, designed with intuitive logic rules based on the clinician experience, performed satisfactorily and outperformed the manual administration in patients in terms of accuracy through the maintenance stage.

1. Introduction

In recent years, the application of computational intelligence to problems in daily life has become more common. Specifically in medicine, where health and safety of patients are involved, the number of researches related to obtain more effective results to improve traditional practices has increased. Since fuzzy set theory and fuzzy logic appeared, the main aim has been developing decision-making systems based on human knowledge in order to apply them to some medical expert systems [1–3].

A fuzzy logic controller is a tool able to evaluate some input information in order to generate an appropriate output based on heuristic knowledge given by the experts. The appearance of this new method included important advantages to classical control engineering, using linguistic characterisation of the quality of controlled process instead of quantitative techniques based on mathematical modelling. Since the first fuzzy control application to a small steam engine [4], the use of fuzzy systems rapidly increased in several domains. Important advancements have been reached in robotic manipulators [5], in nuclear power plants [6], in automotive applications [7] or data management [8–10].

In anesthesia, the interest in automatic infusion systems comes from the expected clinical benefits of improving several aspects of the anesthetic procedure. Automatic systems based on closed-loop structures have been applied in anesthesiology in different

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contexts, for example, neuromuscular blockade [11], hypnosis [12–15] and analgesia control [16,17]. In particular, systems for the administration of hypnotics using automatic procedures based on closed loop systems have been researched [18–24]. The main problem found in traditional closed loop strategies is the difficulty to tune the parameters of the controller because of the interpatient variability. Several adaptive and robust controllers have been developed in order to improve the results obtained [25,26]. However, it is difficult to find an intuitive relationship between the parameters of the controller and the characteristics of the patient.

Using fuzzy logic to translate the clinician expertise into a controller could be an approach to solve this problem. Nevertheless, the application of fuzzy logic inference based controllers for anesthetic infusion has been less studied [27,28]. Most researchers have developed fuzzy controllers based on general rules that evaluate predefined situations but do not continuously consider the hypnotic state of the patient [29]. Hence, the advantages of fuzzy inference systems have not been fully exploited.

The novelty of this research is the design of a complete fuzzy inference system capable of delivering the adequate drug dose according to the hypnotic level of the patient. The rule-base has been totally designed by the clinician, taking into account all possible situations during the surgery and the appropriate actions to perform. Moreover, membership functions and the evaluated variables have been chosen following criteria of the expert. Therefore, no model is explicitly used to design the controller. The model appears implicitly through the clinician experience. As a result, this controller means a natural translation of the expertise knowledge to an automatic medical decision system.

The guidance variable to measure the hypnotic level in our study was the Bispectral Index^{TM} (BIS), a reliable parameter that clinically correlates with the degree of hypnotic component of anesthesia [30]. BIS is a dimensionless index that varies between 100 (awake) and 0 (no electrical activity in brain). In general, a value of 50 is considered appropriate for standard surgical procedures [31]. The drug delivered in our study is propofol. The resulting system will have two functional levels: direct control level and supervision level. For the direct control level, we have developed a closed-loop controller using a Fuzzy Inference System (FIS). The supervision level is responsible to define the target to the control level, the controller setup, alarm management and communication diagnosis. On the one hand, the application of this controller would lead to an increase in patient safety, a reduction in time of use of the operating room and reduction in patient recovery time. It will be a direct consequence of adjusting the dose of drugs according to the real needs of patients. Consequently, a more accurate control of the hypnosis level could prevent the probability of adverse events [32–35]. On the other hand, this new proposed system releases the clinician from routine tasks and allows the interaction between anesthetist and the control level.

To evaluate this method, an observational study is proposed with patients that went through ambulatory surgery. Specifically, the aim is to test the hypothesis that it is possible to translate the expertise of the clinician to a computer based system for drug automation with an improvement of the performance compared to manual administration.

2. Methods

2.1. Description of the fuzzy closed-loop system

The computer based decision system is based on a fuzzy logic controller. The objective of this system is to control the hypnosis level of the patient to reach the BIS target over time, rejecting eventual disturbances. A computer runs the fuzzy controller included in the main program developed for monitoring and controlling BIS signal. As a result, a two-level computer decision system is proposed (see Fig. 1).

On the one hand, a closed-loop controller using a Fuzzy Inference System is designed in the direct control level. Considering the BIS target (50 in this study) and comparing it with the real level of hypnosis of patients given by BIS VISTA monitor (feedback variable), the fuzzy controller calculates the control signal. The computer communicates through a RS232 interface with the actuator, a Graseby 3500 infusion pump with propofol 1% that supplies the drug to the patient according to the control signal.

On the other hand, the supervision level makes possible the interaction between the clinician and the direct control level. The automation of the infusion pump releases the clinician from routine tasks. Consequently, the expert will be able to focus on other variables of the patient. At the supervision level it is possible to define the target of the control level and the controller setup. Moreover, the application includes an alarm module to prevent possible failures in the system (i.e. poor quality in the BIS signal) and follow established protocols to reach a secure mode (i.e. stopping the propofol infusion and commuting to manual mode). The system is periodically updated each 5 s.

2.2. Fuzzy-based computer decision system

From an engineering perspective, maintaining a physiological variable of interest in a desired value is accomplished by using closed-loop control structures: the controlled variable (BIS) is measured and used to calculate the adequate drug dose. This computation can be implemented using different algorithms. In this case it was done using a fuzzy inference system (FIS). A fuzzy controller is an element capable of making decisions in a closed-loop system operating in real time, based on human expert knowledge about the anesthetic process.

Firstly, to define the FIS properly it was necessary to specify the number and type of inputs and outputs to take into account. According to medical criteria, in this FIS, two input variables: BIS error (*BISe*), and BIS change (ΔBIS) and one output variable: infusion rate increment (Δv) were considered. BIS error was computed as $BISe = BIS\text{-}BIS_t$ (where *BIS* is the measured BIS and BIS_t is the BIS target).

Fuzzy logic basis are based on fuzzy sets theory. A fuzzy set in this context is usually a generalization of the concept of interval in the real number line, extending the idea of "belonging to" to a number between 0 and 1 representing membership degree. Each variable is defined though a linguistic variable whose value can reach different linguistic values in order to describe the characteristics of both inputs and output. Let $\tilde{A}_i^j$ denote the jth linguistic value of the linguistic variable $\tilde{u}_i$ defined over the universe of discourse U_i. Linguistic values for variable i are represented by:

$$\tilde{A}_i = \left\{ \tilde{A}_i^j : j = 1, 2, \ldots, N_i \right\} \quad (1)$$

The function $\mu(u_i)$ associated with $\tilde{A}_i^j$ that maps the universe of discourse to [0,1] is called a membership function. This membership function describes the degree of certainty that an element may be classified linguistically as$\tilde{A}_i^j$.

$$\mu_{A_i^j}(u_i) = X \rightarrow [0, 1] \quad (2)$$

A value near 1 indicates that the value is almost fully in the set, and a value near 0 indicates that the value does not belong to that set. For this FIS, triangular membership functions were defined for both inputs and output in a heuristic manner from medical experience. This choice is based on two main reasons: on the one hand, it was easier and intuitive to be modified and studied by the