Improving the Anesthetic Process By Fuzzy Rule Based Medical Decision System

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Abstract*-The main objective of this research is to design and implement 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.*

Keywords-Knowledge-based system ,Fuzzy control Intelligent devices ,Drug delivery ,Anesthesia.

I. 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.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 BispectralIndexTM(BIS), a reliable parameter that clinically correlates with the degree of hypnotic component of anesthesia. 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 procedure. 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 manage 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. On the other hand, this new proposed system releases the clinician from routine tasks and allows the interaction between anesthetist and the control level.

II. METHODS

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.

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.

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 (BIS) and one output variable: infusion rate increment (v) were considered. BIS error was computed as BISe = BIS-BISt (where BIS is the measured BIS and BISt is the BIS target).

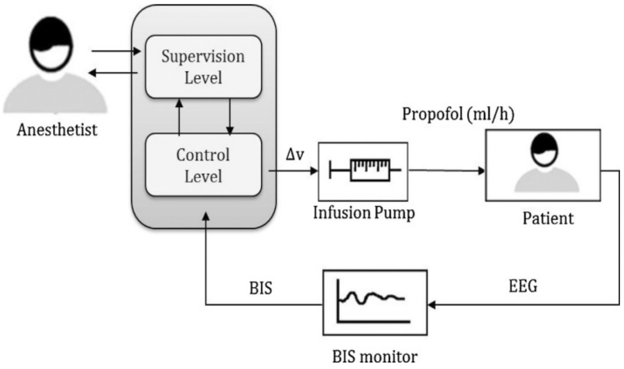
Fuzzy logic basis are based on fuzzy sets theory. A fuzzy set in this context is usually a generalization of the concept of interval in the real number line, extending the idea of “belonging to” to a number between 0 and 1 representing membership degree. Each variable is defined though a linguistic variable whose value can reach different linguistic values in order to describe the characteristics of both inputs and output. Let A˜jdenote the jthlinguistic value i of the linguistic variable u˜idefined over the universe of discourse Ui. Linguistic values for variable i are represented by:

A˜i = A˜i : j = 1, 2, . . ., Ni

The function (u) associated with A˜jthat maps the universe of dis-course to [0,1] is called a membership function. This membership function describes the degree of certainty that an element may be classified linguistically asA˜j.i

Aj (ui) = X → [0, 1]

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 anesthetist, just being defined by three points; on the other hand, it was computationally more efficient. The number of membership functions for each input and output was the minimum to obtain acceptable results to achieve the target of hypnosis according to medical criteria. What is more, increasing the number of membership functions involved increasing computational time and the number of rules without improving the final result.



It is important to note that, as far as the experts were concerned, the BIS input did not reach any value over the ±2 range in practice. That is why the rest of the values along the universe of discourse were saturated. In addition, an “emergence situation” was defined for the v output as an isolated membership function whether BIS were highly negative or BIS reached any value under safety limits predefined. As a result, a considerable decrement was desirable in these cases.

If we consider a fuzzy controller with crisp inputs (BISe, BIS), it is necessary to turn them into a fuzzy value in order to associate them with membership functions of inputs. In this case, to develop the fuzzification process, a singleton fuzzification method was used. Then, the mapping of the inputs to the output is characterised by if-then rules. To design the rules considered in this FIS, the following process was developed:

Firstly, it was necessary to study and analyse data from thirty patients undergoing manual general anesthesia. It was possible to design a previous rule base according to the relation among both inputs and output.

Secondly, anesthetists validated previous rule base and completed it with all possible combinations between inputs following expert knowledge.

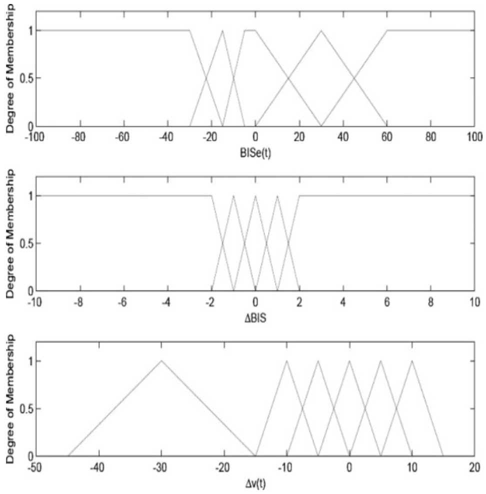
To evaluate each rule, it was necessary to match every fuzzy set obtained from the fuzzification with membership functions of the inputs. The process to obtain conclusions from inputs and rule base is called inference. In this FIS, a Mamdani inference system was developed. As singleton fuzzification was used, the certainty that the i-th rule's premise matches the input information is represented by

$$i(u1, u2, . . ., un)=A1 (u1) * A2 (u1) * . . . * A2 (u1),$$

where the product operation "*" is implemented using the min operator. The result of the inference for the i-th rule is the fuzzy set B̂idefined by the membership function:

$$\hat{B}i (y) =i(u1, u2, . . ., un) * Bi (y)$$

Finally, in order to obtain a numerical value of the output coherently with the rule base and the generalization provided by the fuzzy logic framework, a defuzzification process was performed. As a result, the rule base is a linguistic representation of a receipt to respond to variations in the BIS value by increasing or decreasing the propofol infusion rate. The linguistic representation is a key difference between this FIS and other types of controller, for example Proportional-Integral-Derivative (PID) algorithms, because it provides the designer with the additional advantage of being able to discuss improvements in the controller operation with the field expert, in this case the anesthesiologist, in terms of intuitive rules.Moreover, a FIS includes the mechanisms to work with numerical values in the input to produce numerical values in the output coherently with the rule base and the generalization provided by the fuzzy logic framework. Therefore, the whole system consists of three stages: fuzzification, inference and defuzzification.



Input and output fuzzy partitions of the fuzzy logic controller. Top: BIS Error input. Middle: BIS input Bottom: membership functions for infusion rate increment output.

Design of the observational study

By evaluating the performance of the fuzzy closed-loop system proposed system, an observational study was carried out with 85 patients that went through ambulatory surgery. The surgical procedures chosen were gynaecological, vascular and general surgery. The propofol was infused by means of an automatic device operated by the fuzzy inference system in a group of patients (FCL group). For the rest of patients (control group), the method was the standard manual administration of propofol by an experienced anesthesiologist.

Four patients were finally excluded from the study, one patient in the FCL group due to a haemorrhage at the end of the surgery and 3 patients due to protocol violations, one in the FCL group and two in the control group.

In this case, we have tried to obviate the interaction of opiates to the fullest maintaining a constant perfusion of remifentanil. This also could represent a more stable BIS signal when assessing performance of the controller. Published studies on this interaction [38] Controller output is infusion rate change.set margins where the addition of remifentanil does not introduce changes in its pharmacokinetic or pharmacodynamics behaviour. For this study a moderate remifentanil dose was used in order to obtain an acceptable range of interaction level with propofol.

Statistical analysis

To quantify the performance of the controller, a statistical analysis was developed. Performance Error (PE) is a per sample measurement giving the percentage of deviation from the target BIS. The MDPE (MDPAE) is a per case measurement giving the median of PE (absolute value of PE) in the maintenance stage. The wobble gives the information of intra-individual variability in performance errors. It is defined for i case as:

$$Wobblei=Median\{|PEij - MDPEi|,j = 1\ Ni\},$$

where i =subject number, j =jth(one) measurement of observation period and N = total number of measurements during the observation period.

The global score (GS) is given by:

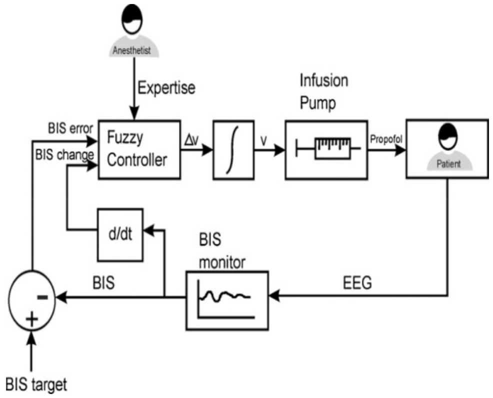
$$GSi= (MDAPEi +Wobblei)/PBIS4060i,$$

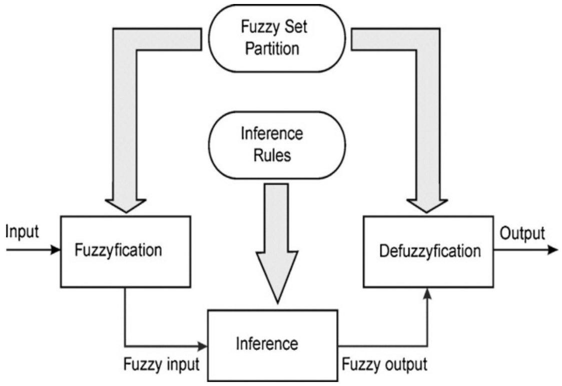
where PBIS4060i is the percentage of time when BIS value is set in the target band (BIS within 40–60 range) during maintenance stage for case i.

Finally, clinical performance parameters represent the percentage of time of the maintenance stage with the BIS value in a particular band. In this study the proposed bands were: excellent (45–55 range), good (40–45 and 55–60), poor (<40 and >60) divided into undershooting (BIS > 60) and overshooting (BIS < 40).

In this paper, results are presented for the main performance measurements using mean value, standard deviation and 95% confidence intervals. The Mann-Whitney U test was applied to obtain a p-value to assess how strongly we can reject the null hypothesis that the medians of the responses in the fuzzy logic based closed-loop system (FCL) group and in the control group are similar.

Data analysis has been carried out with the statistical software R (a Language and Environment for Statistical Computing (R Core Team)). Distribution of sample values were also described using box-and-whisker plots provided by the R software. The box represents the median, the first quantile Q1 and the third quantile Q3. The whiskers outside the box represent the extremes of the distribution excluding the outliers. A point is considered an outlier if it is separated from the box more than the inter-quantile range: IQR = 1.5 × (Q3–Q1).





III. RESULT

This study was approved by the Clinical Research Ethics Committee of “Hospital Universitario de Canarias”. Written informed consent was obtained from all subjects enrolled in the study. Regression analysis using as response variables the main studied parameters (MDAPE, global score, excellent, good, and poor performance, undershoot and overshoot bands) revealed that these confounding variables were not significantly influencing the results.

Remifentanil infusion was administered according to the clinical protocol in 72 patients. In the remaining 9 cases (7 in the manual control group and 2 in the FCL group), there was a need for a transient increase in the remifentanil rate by up to 0.25 mcg/kg/min. The induction phase was similar in both groups. The controller was able to correct eventual deviations of the BIS caused by surgical stimulus. No significant adverse effect was reported in any group. The incidence of hypertension or hypotension was not significant and no differences were observed between groups.

General aspects of the surgical procedure, where duration of anesthesia, time to open eyes once surgery has finished, and propofol consumption are compared for FCL group and control group. There were no significant differences except for propofol consumption that was slightly higher in the FCL group than in the control group (5.69 mg/kg/h vs 4.53 mg/kg/h). It was due to a better adaptation of the supply of drug according to hypnosis level of patients. Therefore, a slightly shorter time to open eyes once surgery has finished was obtained in the FCL group than in the control group (6.81 min vs 7.51 min).

Subsequently, the BIS level decreased until it reached the appropriate value to start the automatic control task. The BIS deviations from the target value were corrected increasing or decreasing the propofol infusion rate according to the rule base defined in the fuzzy controller. As a result, BIS values near BIS target were obtained during the process. The evolution of median, 10th and 90th percentile values for the 42 patients in the FCL group once the automatic control task starts.

It also represent the percentage of the maintenance stage with the BIS in the excellent, good, poor, overshooting and undershooting bands. The results in the FCL group significantly improved the corresponding ones in the control group. Specifically, percentage of time spent in the excellent band for FCL group reached over 50% of total maintenance time, while the percentage in this band for control group did not reach 40%. Despite of these results, the percentage of time in undershooting band was in favour of the control group, however, the difference was not statistically significant. These results are also show the box-and-whisker plots for the excellent, good and poor bands.

Finally,itrepresents parameters related to the performance of the controller. The results for the MDPE, MDAPE and global score parameters showed a significant contrast between both groups in favour of the FCL group.

According to MDPE and MDAPE values, the differences between real BIS of patient and BIS target during the process are lower in FCL group than in control group. In addition, the MDAPE standard deviation showed more spread out values in control group than in the FCL group. This is another evidence of the tendency of the automated system to keep the BIS very close to the target value. In particular, the global score shows an important improvement when the automated system is used.

The analysis of the performance of the FCL was completed by comparing the results with other efficient methods developed. The same parameters related to the performance of the controller were used to compare them. The results of this comparison also demonstrated the potential of our technique, improving percentage oftime in the excellent band as well as reducing the MDAPE coefficient.

IV. CONCLUSION

The observational study together with this comparative analysis revealed a robust performance of the fuzzy inference based controller guided by BIS. The researched system outperformed manual control and when compared to other controllers it offers several improvements, mainly related to maintaining the BIS in the excellent band. These results evidence that it is feasible to develop an automated infusion system using a fuzzy inference controller designed from intuitive logical rules for the control algorithm. This allows the clinician to actively take part in the design of the automatic infusion system and to adapt it to clinical requirements of the specific surgery. With this, the clinician will avoid the continuous interaction with the infusion pump and will be focused mainly on the supervision level.

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