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Automated Blood Pressure Control with Closed Loop System

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***Abstract* —Typical risk reduction measures are not sufficient to reduce the probability of errors resulting from operator mistakes. Improvement of the device software and hardware, adding more alerts and alarms is not enough to significantly reduce the risk of such type of hazards, so there is a need of new methods to improve the safety of medical devices.**

One of possible solutions – systems with closed loop control. Integrating patient monitoring and drug infusion devices in to integrated system and using a controller, which would be able to asses required changes in the infusion according to patients vital signs might make it possible to reduce the probability of hazards arising from the need of constant monitoring, overdose and lack of appropriate timely reaction when a problem occurs.

Modelling of closed loop systems show that the objectives, such as constant blood pressure in post-operative patients, can be achieved. Mathematical modelling is not sufficient to evaluate all the environmental factors, but it is helpful to decide the complexity of the system needed in each case.

***Index Terms*—Closed loop systems, control equipment, fuzzy control, centralized control.**

I. INTRODUCTION

Working time of doctors and nurses is very expensive, so it is very important that most of their attention could be given to patients and detail assessment of their condition, especially in critical cases and not only for routine monitoring of vital signs and devices [1]. This is not always possible, because for example in intensive therapy units there are a lot of monotonous, repetitive monitoring tasks which are very time-intensive. Such tasks include constant checking on patient vital signs, despite that their condition is stable, to determine their reaction to medicine or other treatment. This adds to the increase of personnel fatigue and mistakes due to human factor, especially if there are many patients (especially critical state ones) and so some critical events could be missed [2]. Such situations are impossible to avoid in intensive therapy or emergency units.

In these cases automated medical systems could be beneficial. Such systems could take over repetitive tasks of monitoring, maintenance, data gathering and so on. The decisions of doctors about the desired state of the patient is described in the system, and if the condition of the patient remains stable, no additional labour from the personnel is needed to achieve or maintain desired condition. On the other hand, if some undesirable events occur and the system is not capable of dealing, alarm or alert must be activated and personnel must take charge. For this to be effective, the system must have a simple way to switch to manual mode. As events, which require attention would be rarer, due to the system, constantly monitoring the patient, the personnel would be more attentive when most necessary [3].

This system would differ from the ones used now for monitoring patient vital signs so that it would not only display the parameters in the monitor and record the data for storage, but also react to changes and adjust the dose or speed of the drug infused according to the patient's body reaction. The decision about the treatment, the drugs used, minimum and maximum doses of the drug and infusion speed, and the desirable condition of the patient to achieve and maintain is decided by the clinician and this data is given to the system. If the treatment goes according to plan, the system maintains the chosen parameters. In case of any disturbances, so that the condition of the patient is changed so, that the system by itself is unable to return the patient to the desired (decided by the clinician) state, the alarm is activated and further supervision is carried out by the personnel and the systems is switched to manual mode. Similar systems are being modelled and show promising results [4], [5].

In such case medical personnel would only need to establish the boundaries in which patient parameters could be changed without the risk for patient health and life. According to the state of the patient and the desired condition the clinician can chose from two strategies:

1) *Narrow boundaries for vital sign changes. In this case the predicted amount of infused drugs is possibly bigger, unless the condition of the patient is very stable and does not change in all treatment period;*
2) *Wide boundaries for vital sign changes. In this case, the predicted amount of drugs is possibly lesser, but the vital signs might be not as stable.*

When treatment of each individual patient is considered the clinician can chose the most optimal strategy in between the described extreme strategies, so that the needs of the patient would be satisfied best.

II. DESIGN OF AUTOMATED DRUG INFUSION SYSTEM

Supposed dopamine infusion system is composed of:

1) *Medical personnel;*

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2) *Vital sign sensors and monitors;*
3) *Infusion pumps with management ability;*
4) *Controller for infusion pump management;*
5) *Controller software.*

The sensors for vital sign monitoring and infusion pumps are used in medicine for quite a while now, so the only task which remains is to implement management ability into infusion pumps and to integrate them in to a single system equipped with adequate controller and software to automate the infusion process.

The most important part of the system software is the algorithm for determining required dose for the patient, and it will vary according to the drug, chose for infusion, its effect for the human body and accumulation.

Such system could be useful for infusing dopamine after open heart surgery in post-operative period, when normal systolic blood pressure must be restored and maintained. In these cases constant monitoring and timely correction of the infusion is required to achieve the best results. For post-operative patients the sensor of blood pressure is used, so combining it with the infusion pump and software to evaluate patients sensitivity to drug, the changes in blood pressure and letting this system either make changes in the rate of infusion or to remain with the rate, set by the doctor in the beginning of the treatment seems like a reasonable step for improving the treatment.

In this case the advantage of using automated system instead of manual drug administration is the ability to act not only according to current blood pressure, but using data, gathered in the period of infusion, predict how it will change in the future and correct the infusion rate accordingly. For this to be achieved in administrating the drug manually, much larger resources of personnel are needed. Using automation the sensitivity to the drug could be determined much faster and more precise, and because of that, the required condition of the patient could be achieved using fewer drugs, with benefits to the health for the patient.

For such system to be used in medicine, it must be determined if it is safe and beneficial. One of the ways to do that is risk/benefit analysis, which helps to determine if the device is more beneficial than risky to the patient.

In the case of dopamine delivery system, blood pressure sensors and infusion pumps are widely used for medical practice and their safety and reliability is known and approved, so additional risk of the system arises from the controller and software. The hazards which arise from using the controller might be described as:

1) *Wrong calculations of the infusion rate;*
2) *Rate of calculations is not sufficient;*
3) *Inadequate speed of the system – new dose of the drug is infused before previous starts to take effect.*

The probability of these hazards could be reduced to minimum by using mathematical models and choosing the system parameters so that each variation from normal system behaviour would cause an alarm and further administration of the drug done manually by the personnel.

III. FUZZY LOGIC CONTROLLER

Fuzzy logic differs from other mathematical logic so that linguistic variables can be used for description and mathematically describes partial truth. Fuzzy logic was chosen for the development of dopamine infusion system (the algorithm of the close loop system is shown in Fig. 1.), because the rules of it allows to easily use human expert experience and make automated infusion as close to administered by the medical personnel as possible. Similar systems with fuzzy logic controllers are developed and the results show promise [6]. The objective of the system (the plant in a control theory) is the patient, and usually the reaction to the drug id nonlinear, hard to predict and different in each individual case, using fuzzy logic allows describing a wider spectrum of actions without adding too complicated algorithms and making the system accurate enough.

The objective of this research is to create a system, which would be flexible enough for the purpose of treatment, and with the ability to choose as many parameters as needed, but also easy to use and intuitively understandable for the personnel, with an acceptable risk/benefit ratio, and reliable.

Fig. 1. The algorithm of the close loop system.

For the fuzzy logic based controller, the main parameters are the rules used for describing appropriate actions (rule base) and linguistic variables used in those rules. In the dopamine infusion system the objective is systolic blood pressure, which can be “low”, “very low’’ and “normal”. As the system does not deal with a blood pressure that is too high (only one drug is infused), there is no such variable as “high”. The blood pressure dynamics is also an important variable, which can be described as “pressure change” being “fast”, “”medium”, “slow”. The outcome of the controller is the dose of the dug, in this case, dopamine, to be infused for the patient. The dose must have reasonable limits, which are set by the clinician to avoid overdose, and the exact amount can be different in each case. In modelling the system, statistical averages were used as these values are the most common. The rules describing the modelled controller are as follows:

1) If the blood pressure is low and the change is slow, the dose is large;
2) If the blood pressure is low and the change is medium, the dose is medium;
3) If the blood pressure is low and the change is fast, the dose is large;
4) If the blood pressure is medium and the change is slow, the dose is medium;
5) If the blood pressure is medium and the change is medium, the dose is medium;
6) If the blood pressure is medium and the change is fast, the dose is zero;
7) If the blood pressure is normal and the change is slow, the dose is medium;
8) If the blood pressure is normal and the change is medium, the dose is zero;
9) If the blood pressure is normal and the change is fast, the dose is zero.

The task to decide the values of “normal” blood pressure, which can differ from patient to patient is left for the clinician, as well as the doses of the drug infused. The variable overlap in many cases as in treatment it is not always reasonable to seek to achieve the exact value.

In modelling this system real patient systolic blood pressure after open heart surgery was used for reference (Fig. 2.).

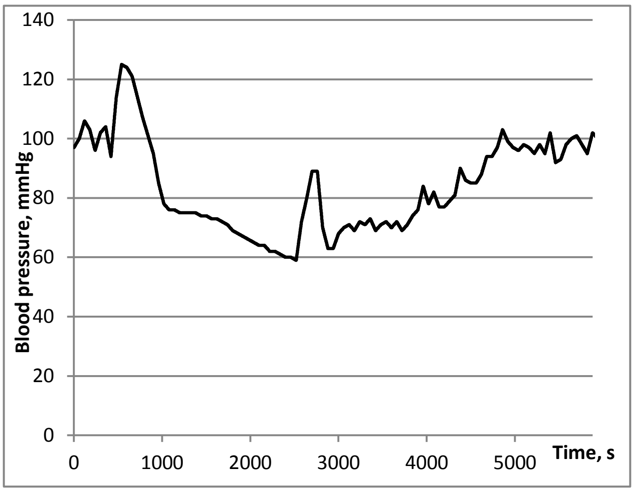

Fig. 2. Systolic blood pressure after open heart surgery (first 24 hours).

Dopamine is used to regulate blood pressure and it is usually administered manually according to the data of blood pressure sensors. Constant monitoring is needed first twenty four hours after the surgery but sufficient monitoring is very labour intensive and not always possible due to lack of personnel.

IV. MODELLING THE SYSTEM IN MATLAB SIMULINK

Fuzzy logic based controller (Fig. 3.) maintains a systolic blood pressure equal to 100 mmHg. First 24 hours after open heart surgery are shown. As the system does not have any means to lower the blood pressure, blood pressure above 100 mmHg remains uncontrolled.

In Fig. 4. the value of “normal” blood pressure is not a number, but an interval of 80 – 100 mmHg, which is more reasonable for real system. Due to delays in the system, the blood pressure, which is over the given value of 100 mmHg is raised less in this case, which is usually more acceptable. In cases, when the blood pressure must be raised as quickly as possible, narrower boundaries could be suggested, but there is a bigger risk of overdose.

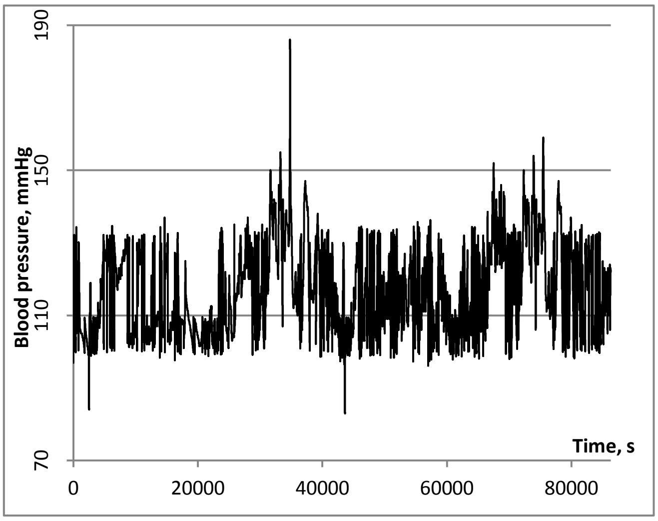

Fig. 3. Blood pressure control by the system with fuzzy logic controller when the set value is 100 mm Hg.

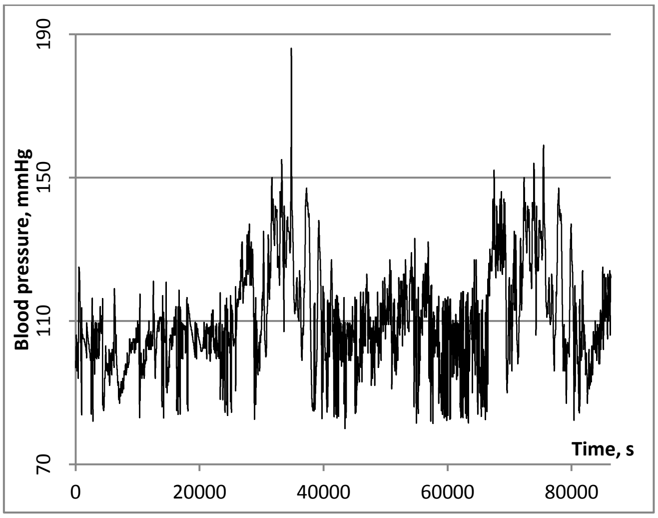

Fig. 4. Blood pressure control by the system with fuzzy logic controller when the set value is 80 – 100 mm Hg.

Also included in modelling was a different reaction time of the patient and the system (Fig. 5). A bigger delay (for example, of 10 minutes) is preventing the system from timely reaction to blood pressure changes and therefore it drops below required value more times than with lesser delay.

Such delays are not a drawback for systems, which can adapt after first hours of infusion to individual reactions of the patient and delays, which may be different in each case. Even if the delay cannot be compensated by the system and causes a higher blood pressure than expected, the system is still superior to manually administered drugs in many cases, as the reaction to changes is still better. Different patient reactions to infused drugs are modelled and presented in Fig. 6.

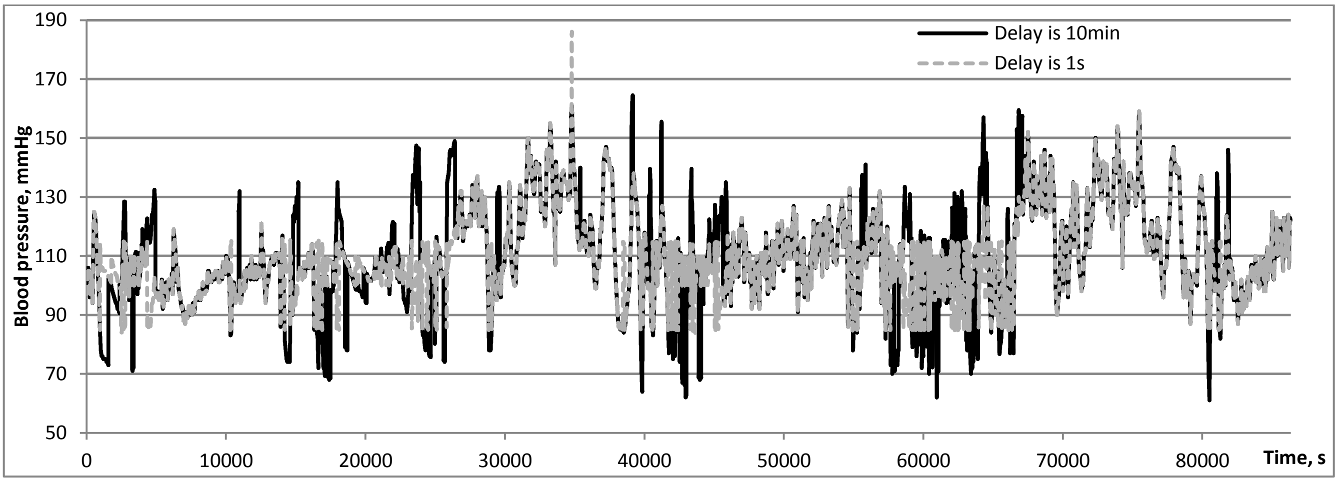

Fig. 5. Blood pressure control by the system with fuzzy logic with different reaction delay to drug.

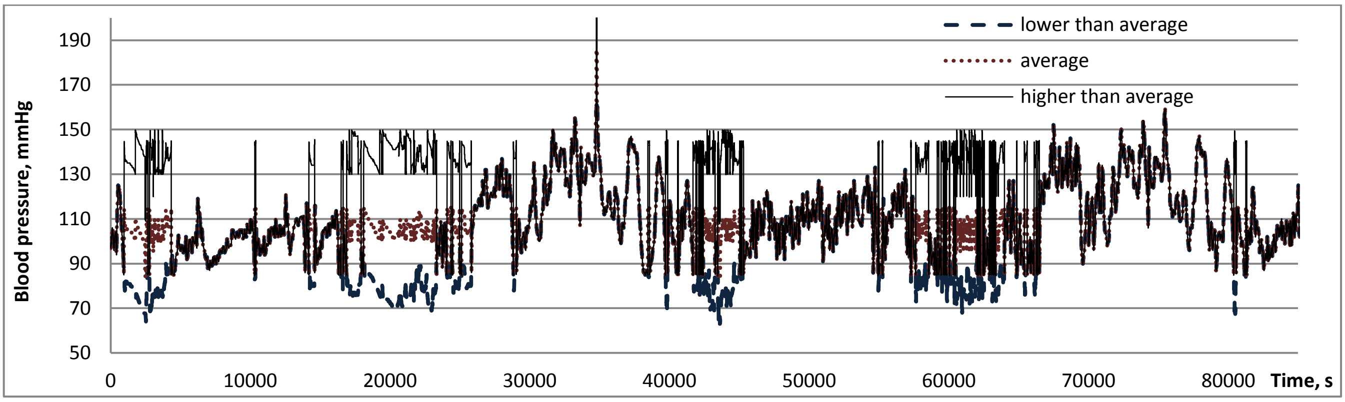

Fig. 6. Blood pressure control by the system with fuzzy logic controller with different reaction to drug.

CONCLUSIONS

Simulation results show that the system with the closed loop and fuzzy logic controller are able to maintain the systolic blood pressure of the patient after open heart surgery.

Blood pressure changes depend on system reaction delay, so this parameter should be taken in to account very responsibly to avoid overpressure.

Patient reaction to drug has less effect than reaction delay, so by selecting correct dose (by adapting system) this effect might be eliminated.

Simulation does not evaluate all the factors that might influence the real working system, but it helps to determine the parameters of the system for it to be able to carry out the tasks set.

The main objective of further research of this topic is to include a wider spectrum of possible patient parameters, as average values do not cover a sufficient part of system users in real life. Focusing on marginal parameters, as well as an ability of the controller software to quickly adapt to each individual case might help develop a safer system.

Safety of any medical system is always a major concern in creating such new devices, so not only technical parameters, but also particularities of destined system operators (clinical personnel without a technical education) should be taken in to consideration in as early stage of design as possible.

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