Fuzzy logic control for intracranial pressure via continuous propofol sedation in a neurosurgical intensive care unit

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Abstract

The major goal of this paper is to provide automatically continuous propofol sedation for patients with severe head injury, unconsciousness, and mechanical ventilation in order to reduce the effect of agitation on intracranial pressure (ICP) using fuzzy logic control in a neurosurgical intensive care unit (NICU). Seventeen patients were divided into three groups in which control was provided with three different controllers. Experimental control periods were of 60 min duration in all cases. Group A used a conventional rule-based controller (RBC), Group B a fuzzy logic controller (FLC), and Group C a self-organizing fuzzy logic controller (SOFLC). The performance of the controllers was analyzed by ICP pattern of sedation. The ICP pattern of errors was analyzed for mean and root mean square deviation (RMSD) for the entire duration of control (i.e., 1h). The results indicate that FLC can easily mimic the rule-base of human experts (i.e., neurosurgeons) to achieve stable sedation similar to the RBC group. Furthermore, the results also show that a SOFLC can provide more stable sedation of ICP pattern because it can modify the fuzzy rule-base to compensate for inter-patient variations.

Keywords: Intracranial pressure; Neurosurgical intensive care unit; Rule-based controller; Fuzzy logic controller; Self-organizing fuzzy logic controller

1. Introduction

Many patients admitted to an intensive care unit (ICU) will require continuous sedation at some point during their stay in the ICU. The goal of sedation is to reduce anxiety, control agitation, and produce a patient who is calm, cooperative, and able to communicate. In well-designed clinical trials with patients receiving sedation in an ICU for a variety of indications, propofol provided adequate sedation for a similar proportion of time to midazolam [1]. Studies in patients with traumatic brain injury have shown that propofol reduces agitation-triggered surges in intracranial pressure (ICP), and prolonged reduction of ICP after bolus injection of propofol has also been documented [2]. Thus, when controlling ICP in the ICU in a variety of clinical contexts, propofol provides effective sedation with a more rapid and predictable emergence time than other drugs.

Closed-loop control in medicine emerged as a serious contender for many forms of control in the late 1970s. It was pioneered by Sheppard et al. [3] and Asbury et al. [4] who demonstrated through clinical experiments that this form of control is safe, effective and in many cases better than manual control. However, one problem with feedback control in biomedicine is that there are large patient-to-patient variations in dynamic model parameters. This is compounded by large time-varying parameters for an individual patient during the course of an operation, making it difficult to design a fixed-parameter PID controller suitable for all cases. This leads to the need to investigate self-adaptive control strategies, and subsequent self-organizing controllers. Although self-tuning controllers have been successful, they involve...
2. Control target of ICP pattern for sedation

Anxiety, agitation, delirium, and pain are commonly experienced by ICU patients. These states may lead to increased irritability, discomfort, hypotension, tachycardia, cardiac ischemia, harmful motor activity, and psychological disquiet. The appropriate treatment of these conditions may lead to decreased morbidity and mortality among the critically ill. Regarding the treatment of severe head injuries, there is consensus concerning many aspects of initial management, such as controlled ventilation, blood volume substitution, and early evacuation of focal intracranial mass lesions, and ICP is continuously monitored in most neurotrauma centers. However, opinions differ widely on the various treatment protocols for sustained increase in ICP in order to achieve good sedation [17]. Therefore, how to define the ICP pattern for sedation is the most important part of this system.

2.1. ICP pattern for sedation

In the neurosurgical intensive care unit, a variety of activities, such as nursing activities, coughing, and agitation, all produce transiently higher ICP. In this preliminary study, nursing activities were avoided during the control period. Hence, the signal processing of the ICP signals requires extraction of the actual brain’s response caused by agitation from accompanying coughing and noise. In many severe head-injured patients, there is a natural progression of physiologic states from the time of injury, or onset of disease, through recovery or death [18]. The physiologic state of the patient may shift rapidly from a compensated physiologic state to an uncompensated disease state. There are physiologic transition zones between compensated and uncompensated disease states, and that these transition zones may be detected by a careful analysis of physiologic signals [19].

Such detection could be accomplished via the recording of a great number of signals and the computations of the ensemble average. When we record an ICP signal, which is, or might be, changeable, the method of moving averages can be used [20]. The main shortcoming of the method is the trade-off between using a large window for sufficient coughing and noise reduction or a small window for preservation of agitated ICP rapid changes. The problem lies in the operation inside the sliding window since the performed signal averaging is sensitive to artifacts whenever a small number of trials are to be processed. Even if an on-line artifact rejection routine is activated, the low-amplitude artifacts can escape, deteriorating the estimate of the ICP signals. Therefore, a large window is needed, but in this way ICP changes are smoothed out and may become undetectable [21]. According to consultation with NICU neurosurgeons, we chose the average ICP of the last 5 min (MA_5) to serve as the extraction of the actual brain’s response caused by agitation from accompanying coughing and noise. Moreover, we chose the average ICP of the last 30 min (MA_30) to be the baseline of natural progression of physiologic states.

Furthermore, the factors for propofol sedation control are dependent on the intracranial adaptive capacity [22,23]. Hence, assessment of intracranial adaptive capacity is vital in critically ill individuals with acute brain injury because there is the potential that nursing care activities or environmental stimuli may result in clinically significant increases in intracranial pressure in a subset of individuals with decreased intracranial adaptive capacity. ICP waveform analysis provides information about intracranial dynamics that can help identify individuals who have decreased adaptive capacity and are at risk for increases in ICP and decreases in cerebral perfusion pressure, which may contribute to secondary brain injury and have a negative impact on neurologic outcome. Therefore, the difference of the change in mean values of ICP between the average ICP of the last 5 and 30 min (i.e., ΔMA = MA_30 − MA_5) is calculated and used a main factor for sedation control in this paper. Also, the ability to identify high-risk individuals allows neurosurgeons to...
initiate interventions targeted at decreasing adaptive demand or increasing adaptive capacity in these individuals [24]. This initial intervention targeted value is the same of the tolerance of the $\Delta$MA values (i.e., $\Delta$MA Tol) defined in this paper and is strongly dependent on the average ICP of the last 30 min (i.e., MA 30). If the MA 30 value is higher, the tolerance of the $\Delta$MA value (i.e., $\Delta$MA Tol) is lower, which means decreased intracranial adaptive capacity. The relationship between this tolerance of $\Delta$MA and the MA 30 value is shown in Fig. 1.

2.2. The assessment of ICP pattern of sedation

After defining the ICP baseline (i.e., MA 30 value), the ICP pattern for sedation (i.e., MA 5 value), the change in mean values of ICP (i.e., $\Delta$MA = MA 5 $-$ MA 30), and the tolerance of the $\Delta$MA value (i.e., $\Delta$MA Tol), then the problem of how to validate this controlling performance arises. In this paper, the performance of the controllers was analyzed by ICP pattern of sedation. The ICP pattern of errors (measured $\Delta$MA value $-$ $\Delta$MA Tol value) was analyzed for mean and root mean square deviation (RMSD) for the entire duration of control (i.e., 1 h) [14]. Mean (S.D.) propofol infusion rates delivered every 0.5 min (i.e., sampling time) during control in each individual case were also calculated. These values for 10 cases of each group were then analyzed and expressed as mean (S.D.) and range.

3. Control system design

3.1. Rule-based controller via neurosurgeons’ experience

The most commonly used drugs for sedation are propofol and thiopentone. Propofol is justified by some of its properties, such as its short onset time and quick recovery, which have led it to gain considerable popularity over other agents, such as thiopentone. Generally speaking, the basic principle of giving a sedation drug in a NICU is that one should control the ICP value followed the movement of the trend of the ICP value. According to the definition in Section 2, we use MA 5 as the ICP pattern and MA 30 as the ICP baseline (i.e., the trend of ICP movement). Hence, the strategy is always to give a small dose (i.e., an increase by 30% over the previous infusion rate) first when the MA 5 $-$ MA 30 larger than the tolerance, judge its effects and then add more as required. When the MA 5 $-$ MA 30 less than the tolerance, it means the ICP has decreased and the propofol rate should be reduced according to pharmacological reasons. After consultation with NICU physicians, the rule-base in the following statements comes from formal protocol of neurosurgeons’ clinical experience.

Rule-base of the sedation drug of propofol (i.e., 10 mg/ml concentration):

- Maintenance of infusion at 8 ml/h at the beginning:
  1. IF $\Delta$MA $\leq$ tolerance of $\Delta$MA THEN
     a. After 0.5 min, reduce by 1% of previous infusion rate.
     b. After another 0.5 min, reduce by 1% of previous infusion rate again.
     Until reaching minimum infusion rate of 4 ml/h.
  2. IF $\Delta$MA $>$ tolerance of $\Delta$MA THEN
     a. After 0.5 min, increase by 30% of previous infusion rate.
     b. After another 15 min (i.e., lockout time for 15 min), increase by 30% of previous infusion rate again.
     Until reaching maximum infusion rate of 15 ml/h.

3.2. Design of drug control using a FLC algorithm

Fig. 2 shows the FLC control structure of the sedated patient in NICU. The propofol infusion rate is adjusted according to a lookup table, which is designed using fuzzy logic. Control rules, membership functions, fuzzy inference engine, and defuzzification are the essential elements in the fuzzy logic control. To perform fuzzy inference and describe this FLC control system, we chose two inputs, which were the patient’s ICP value and the $\Delta$MA (i.e., MA 5 $-$ MA 30), and one output which was the change in propofol infusion rate ($\Delta$Infusion Rate). In order to fuzzify the inputs and output, the ICP value was divided into three levels, namely small (S)
between small and big (SB), and big (B). There is no negative fuzzy set because of the non-feasible nature of ICP. The ΔMA was divided into five levels, namely zero (Z), between zero and small (ZS), small (S), between small and big (SB), and big (B). Moreover, there is no negative fuzzy set because we stop reducing the infusion rate and maintain the previous infusion rate, according to the neurosurgeons’ experience. The change in propofol infusion rate was divided into five levels, namely negative big (NB), negative small (NS), zero (Z), positive small (PS), and positive big (PB). There are many shapes of possible membership functions, such as triangle and trapezoid, which can be used in the fuzzy logic controller. In this study, a triangular shape is used and a 25% overlap for contiguous fuzzy sets is reckoned [27], as shown in Fig. 3, for two inputs (ICP and ΔMA), and one output (ΔInfusion_Rate). According to the neurosurgeons’ experience, nine rules were developed to control the sedated patient system, as shown in Table 1. Although these initial rules can control the sedation of most of the patients in the NICU, some of these rules need to be modified due to inter-patient variations. Hence, this could be done using a SOFLC algorithm to further fine-tune this rule-base.

### 3.3. Design of drug control using a SOFLC algorithm

SOFLC is an extension of a simple fuzzy logic controller with the self-organizing level that incorporates the four new functional blocks shown in Fig. 4: (1) the previous rule-base generation; (2) the performance index; (3) the rule-base modification algorithm; (4) the control rule-base performance measure.

#### 3.3.1. The previous rule-base generation

This rule-base can be generated either from expert experience (i.e., neurosurgeons) or from learning input and output data. In this paper, we keep the initial rule-base (i.e., nine rules as shown in Table 1) from expert experience using previous rule-base generated from simple FLC. After introducing several data into the process, the previous rule-base will be modified by current input and output data.

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**Table 1**

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<th>ΔMA</th>
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ICP: intracranial pressure; ΔMA: the value of MA_5 - MA_30; Z: zero; ZS: between zero and small; S: small; SB: between small and big; B: big; NB: negative big; NS: negative small; PS: positive small; PB: positive big.
3.3.2. The performance index

The performance index measures the deviation from the desired response and calculates the appropriate changes that are required in the output of the controller. The generation and modification of control rules is achieved by assigning a credit or reward value to the individual control actions that make a major contribution to the present performance. The credit value is obtained from a fuzzy algorithm, which defines the desired performance linguistically and has the same form as the control algorithm of the generic fuzzy logic controller [13]. Hence, these linguistic performance rules are derived from a qualitative “feel” for the process and are intended to provide fast convergence around the equilibrium state to achieve high accuracy. For this reason, it is not specific to the type of process being controlled. In other words, this performance index may be very similar for each process. In this paper, the performance index was derived from previous research [13], as shown in Table 2.

3.3.3. The rule-base modification algorithm

The method of logic examination [28] can be employed to obtain the conflicting rules. Conflicts can arise in three different ways. They may come from noisy data, they may be a result of unsuitable data quantization, or they may mean that the proposed structure for the model is incorrect. With rules obtained from input and output data, one can calculate the possibility for each rule. If there are any conflicting rules, one can compare the rule possibilities and retain the one with the largest possibility [29]. However, in this paper, we keep the initial rule-base (i.e., nine rules as shown in Table 1) from expert experience all the time and only calculate the possibility of the new rules (i.e., not in the initial nine rules) generated from coming input and output data.

3.3.4. The control rule-base performance measure

After modifying the three functional blocks, the control rule-base becomes accurate (i.e., no noise contamination or conflicting rules). If the performance of the controller is satisfied by the necessary criteria (i.e., $\Delta MA \leq$ tolerance of $\Delta MA$ in our system), which is strongly dependent on individual system requirement, the rule-base of the controller will stop modification and the rule-base will converge to a constant rule-base.

Hence, in the drug controller design for regulating ICP using a SOFLC algorithm, the two input variables were chosen to be ICP and $\Delta MA$, while the output was the drug controller output. As shown in Fig. 2, the fuzzy sets, the shape of membership function, the inference engine and the defuzzification procedure were the same as those in the previous section on FLC. As shown in Table 1, the initial rules chosen were the same as those in Section 3.2 on FLC. Then, the rules were obtained via the self-organizing level. Regarding assessment of SOFLC quality for propofol drugs, we compared the results of this method with both RBC via neurosurgeons’ experience and FLC.

4. Patients and methods

Seventeen patients aged 19–82 years with severe head injury (i.e., initial Glasgow coma score [GCS] $\leq$ 8), mechanical ventilation, and unconsciousness and undergoing different neurosurgeries were studied in the NICU of National Taiwan University Hospital, Taipei, Taiwan. The study was approved by the Local Ethics Committee, and written informed consent was obtained from the next of kin of all patients. They were divided into three groups so that we could compare the clinical assessment of ICP and the amount of propofol drug consumption using the rule-base from neurosurgeons’ experience and the new technology of FLC and SOFLC, which has been very successfully applied over the past 3 decades.

Patients assigned to Group A were controlled using a conventional RBC. This group consisted of two female and three male patients. Their median initial GCS was 8 (range 7–8) and median age was 61 (range 51–68) years. Two data collection and control sessions under different conditions were performed for each patient. In Group B, which contained six patients, an FLC technique was used. The group consisted of three female and three male patients with a median initial GCS of eight (range 6–8) and median age of 58 (range 19–82) years. One patient underwent three data collection and control sessions, two patients had two sessions and three patients had one session each. In Group C, a SOFLC controller was used. Group C consisted of six patients (two females, four males), median initial GCS 7 (range 6–8), median age 48 (range 26–81) years. Four patients underwent two data collection and control sessions and two had only one session.

The NICU is equipped with Hewlett Packard (HP) bedside monitors. There are several modules to plug into this bedside machine for monitoring the physiological data of the patient, including mean arterial pressure (MAP), heart rate (HR), and end tidal CO2 (EtCO2), which are routine monitoring parameters, as well as ICP, which is not yet a routine monitoring parameter. For ICP monitoring, the Codman neuromonitor interface control unit, catalog no. 82-6605, is a passive interface between the Codman ICP

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<th>ΔMA</th>
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| SOFLC self-organizing fuzzy logic controller; ICP: intracranial pressure; ΔMA: the value of $MA_{\text{f}} - MA_{\text{i}}$; Z: zero; ZS: between zero and small; S: small; SB: between small and big; B: big; NB: negative big; NS: negative small; PS: positive small; PB: positive big. |
microsensor and the Hewlett Packard bedside monitor. Meanwhile, a Graseby 3500 syringe pump for monitoring and controlling the propofol infusion rate is used in this system. For this paper, an on-line closed-loop feedback control system, which was built on notebook, syringe pump, and bedside monitor, was designed to achieve the medical automation in NICU. The digital communications were done via two RS232 serial ports that were interfaced to the Hewlett Packard bedside monitor and the Graseby 3500 syringe infusion pump. In all cases the sampling time was set to 0.5 min (i.e., controlling the propofol infusion rate changed every 0.5 min) and the duration of control for each case was set to 60 min.

5. Results

Table 3 shows the performance of ICP pattern of sedation according to raw ICP values analyzed using mean ICP errors and root mean square deviation of ICP errors, and the mean infusion rate of propofol for the entire duration control. The system achieved stable sedation with mean ICP errors (S.D.) of Groups A–C by $-4.3 \pm 0.9$, $-4.1 \pm 0.6$, and $-3.0 \pm 1.4$ mmHg, respectively, and with RMSD of ICP errors (S.D.) of Groups A–C by 4.4 (0.8), 4.7 (1.2), and 3.3 (1.4) mmHg, respectively. In addition, the mean infusion rate (MIR (S.D.)) of Groups A–C were 5.11 (0.62), 6.75 (2.93), and 7.30 (2.78) ml/h. For mean and RMSD of ICP errors, the values of SOFLC group were significantly lower than those of RBC and FLC groups ($P < 0.05$). Nevertheless, as seen in Table 3, the controller performance of SOFLC in terms of mean and RMSD of ICP errors is significantly lower than those of RBC and FLC groups ($P < 0.05$). The results show that a SOFLC can provide more stable sedation of ICP pattern because it can modify the fuzzy rule-base so that inter-patient variations can be taken care of. Finally, the full graphical results from one clinical trial (i.e., patient 1 from the SOFLC group) are shown in Fig. 5 to demonstrate the monitoring of ICP value, the calculation of the control target of sedation and the evaluation of controller performance from ICP pattern of errors, and propofol infusion rate.

Table 3

<table>
<thead>
<tr>
<th>Value</th>
<th>RBC (n=10)</th>
<th>FLC (n=10)</th>
<th>SOFLC (n=10)</th>
<th>P-value</th>
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<td>ICP pattern of error (mmHg)</td>
<td>$-4.3 \pm 0.9$</td>
<td>$-4.1 \pm 0.6$</td>
<td>$-3.0 \pm 1.4$</td>
<td>0.018</td>
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<td>ICP pattern of RMSD (mmHg)</td>
<td>4.4 (0.8)</td>
<td>4.7 (1.2)</td>
<td>3.3 (1.4)</td>
<td>0.029</td>
</tr>
<tr>
<td>MIR of propofol (ml/h)</td>
<td>5.11 (0.62)</td>
<td>6.75 (2.93)</td>
<td>7.30 (2.78)</td>
<td>0.102</td>
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Table 4

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<th>Case number</th>
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<th>Linguistic rules</th>
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<th>$\Delta MA$</th>
<th>$\DeltaŞInfusionRate$</th>
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6. Discussion

In this paper, using a fixed rule-base, we have demonstrated that fuzzy logic control is appropriate for controlling the sedation of patients in the NICU similar to control by experts (i.e., neurosurgeons). In addition, by incorporating a self-organizing layer to the fuzzy logic controller, it becomes a hierarchical controller in the real-time clinical situation for on-line generation and modification of the rule-base for individual patients so the controller can be finely tuned. It has been argued that it is unsafe to start control with a blank rule-base [13], because the process output value may move to a region of the fuzzy rule-base, where no control rule is available for execution. Our self-organizing hierarchical controller starts with a previous fuzzy logic controller rule-base in order to make sure that it is safe to start. We keep the initial rule-base (i.e., nine rules) from expert experience all the time and only calculate the possibility of the new rules (i.e., not in the initial nine rules) generated from coming input and output data. The ICP and ΔMA values were divided into 3 and 5 levels so that the maximum rules of this rule-base are 15. If we deduct the initial nine rules from expert experience, there is a maximum of only six new rules. Although the derivation of fuzzy rules is a common bottleneck in the application of fuzzy logic controllers, it is still easy to determine the extreme cases of rules, which are always located in the four corners of the lookup table. However, in the gray area, such as in the middle of the lookup table, it is more difficult to decide according to experts because it may strongly depend on each individual patient. In our paper, the new six rules, which are not in Table 1, are all located in middle of the lookup table. After 10 cases of SOFLC clinical trials and filling in new rules from Table 4 into Table 1, four new rules were generated. They are: (1) if ΔMA is ZS and ICP is S then ΔInfusion_Rate is Z; (2) if ΔMA is ZS and ICP is SB then ΔInfusion_Rate is Z; (3) if ΔMA is ZS and ICP is S then ΔInfusion_Rate is S. These four new rules may be needed for controlling the ICP via continuous propofol sedation in NICU. However, a large series of clinical trials is still necessary in order to complete the rule-base. Moreover, we also see in Table 4 that different new rules are generated (i.e., one or two rules) for each case. Hence, the most important part of SOFLC is to provide on-line fine-tuning fuzzy rule-base so that inter-patient variations can be considered.
In this paper, we did not optimize any factors both in either RBC or FLC. The factors used in these two methods are all based on neurosurgeons’ clinical experience and rule of thumb in the fuzzy logic. For example, the initial rule-base (i.e., nine rules) from Table 1 was obtained after discussion with neurosurgeons. However, it was still too subjective, which is why we need to use the SOFLC to optimize the one factor (i.e., rule-base) during on-line clinical trials. However, it can be generated by the self-organizing fuzzy modelling (SOFM) algorithm [29] according to routine clinical control of propofol sedation. The SOFM algorithm is derived from a traditional SOFLC algorithm. It can automatically obtain rules from input and output data and has been applied to controlling the depth of anesthesia via auditory evoked response [30]. Moreover, although a SOFLC can provide more stable sedation of ICP pattern than those of RBC and FLC groups, it still has plenty of room to reach an even better control performance. Not only the fuzzy rule-base but also membership functions, fuzzy inference engine and defuzzification can be adapted to those of their parameters or methods via artificial intelligence techniques for each individual patient. This will administer more propofol and change the rate of delivery more often when an error is seen. Currently, fuzzy logic, neural networks and genetic algorithms are three popular artificial intelligence techniques that are widely used in many applications. Due to their distinct properties and advantages, they are currently being investigated and integrated to form models or strategies in the areas of system control. In control engineering, the fusion of fuzzy logic, neural networks and genetic algorithms is steadily growing [31–33]. Therefore, using the hybrid intelligent approach to autotuning the parameters of the fuzzy logic controller may provide more suitable clinical ICP pattern control in the NICU.

7. Conclusion

In this preliminary study on automatically continuous sedation control of ICP pattern in the NICU, we have demonstrated that FLC can easily mimic the rule-base of human experts (i.e., neurosurgeons) to achieve stable sedation similar to the RBC group. Furthermore, the results also show that a SOFLC can provide more stable sedation of ICP pattern because it can modify the fuzzy rule-base so that inter-patient variations can be considered. This can be seen as a demonstration of feasibility and comparison of the applicability of RBC, FLC, and SOFLC for sedation control of ICP with severe head injury at NICU. However, a longer series of clinical trials at NICU is still needed, perhaps to refine the rule-base, and certainly to see how widely the rules are applicable. Especially, the cross-over design needs to be considered into methodology in order to enable comparison of different behaviours of the same patient tested in different algorithms. Therefore, this presentation is by no means complete and it aims primarily to give an idea of whether FLC is able to mimic a human controller (i.e., rule-based controller) and whether SOFLC can provide a better controller performance when the rule-base can be modified. Furthermore, the current research can now be expanded to encompass alternative sedative techniques and different sedative drugs (e.g., Midazolam, Lorazepam). In addition, this SOFLC algorithm could be expanded to include other closed-loop control in the NICU, such as muscle relaxation control of an atracurium drug and even more complex multivariable control problems, such as the treatment of cerebral perfusion pressure (CPP = MAP – ICP) for controlling MAP and ICP in NICU [34].

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