Close-loop Administration System Based on Bispectral Index for Anesthesia of ERCP

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Abstract. Objectives: To analyse the safety and efficacy of venous propofol sedation with close-loop administration system based on bispectral index (BIS) in elderly patients during endoscopic retrograde electroencephalography (ERCP). Methods: Selected 150 consecutive elderly patients undergoing EPCP procedures, anesthesia by propofol sedation of close-loop administration system with BIS target at 60. Patients were divided into 3 groups according to their age: group A, 50-70 years old (n=50); group B, aged 71-80 (n=50); group C, older than 80 years (n=50). Propofol dosage and adverse events (hypotension and hypoxaemia) during ERCP were the prime data to be recorded. Results: Lower target concentration of propofol might be more suitable for older patients. Median target concentration are respectively 2.6µg/mL, 2.1µg/mL and 1.6µg/mL for the three groups. Hypo-tension is more commonly happened in the younger group, and the incidence of hypoxaemia is significantly higher in the older groups, although the amount of adverse events was small. Low preoperative systolic blood pressure (<80 mm Hg) was more possible turned into peri-operative hypo-tension, patients with abnormal pulmonary function was associated with hypoxaemia in groups B and C. Conclusions: Close-loop administration system is stable and dependable for intravenous anesthesia for ERCP. Lower dosage of propofol is suitable for elderly patients with the same target BIS of 60 More attention of hypoxaemia should be paid to the elderly patients, particularly with abnormal pulmonary function.

Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is commonly management for many pancreatobiliary disorders, common bile duct stones, pancreatic cancer for instance. Compared with upper gastrointestinal endoscopic procedures, ERCP is more time-consuming and sophisticated procedure with ventricumbent position or semi-pronation that might be rough for anesthesia doctor to handle complication [1]. Elderly patients undergoing ERCP may be vulnerable for adverse events during sedation and in the postoperative period [2].The most common complications in ERCP with sedation including hypo-tension, vasovagal episodes, hypoxaemia, hypo-ventilation, airway obstruction, apnoea and arrhythmia [3].

Elderly patients are supposed to be anesthesia by lower dosage of sedation to achieve equal pharmacological effects compared with younger patients. A target-controlled infusion(TCI) system, which is the computer-assisted pump enables automatically administrate sedative drugs according to algorithm of pharmacokinetics of effect-site organ [4]. However, the pharmacokinetic model in the TCI pump may not be extraordinary optimal and personal for each individual patients especially for advanced age and concomitant disease [5]. Bispectral index (BIS) monitoring is an electroencephalography based method that quantifies the depth of anesthesia by analyzing the electroencephalogram and uses a complex algorithm to generate an index score, providing an objective measurement of consciousness[6]. However anesthesia doctor need to always adjust the target of TCI to maintain stable BIS for volatile stimulate of procedure, that means potential
exposure to radiation. Recently, the utility of the combination of a TCI pump and BIS monitoring close-loop system with stable BIS target for endoscopic treatment was reported for operation [7]. However, there is limited information on the outcomes of close-loop administration for sedation of ERCP patients with different age. This study aimed to evaluate the safety and efficacy of BIS based close-loop system with target control infusion of propofol for patients during ERCP procedure.

Methods

Patients and Study Design

150 consecutive selective ERCP patients were enrolled at the endoscope center of China-Japan union hospital of Jilin university between October 2016 and September 2017. The sedation proposal is intravenous infusion of propofol with a TCI system with stable BIS 60 controlled by close-loop system. Patients were divided into 3 groups according to ages: group A, 50-70 years old (n=50); group B, aged 71-80 (n=50); group C, older than 80 years (n=50). Basic information of each patient were calculated, such as gender, body mass index, respiratory function, NIBP, HR, SpO2.

Medication and Monitoring

Pharyngeal anesthesia was performed with 2% lidocaine topical spray before intravenous infusion of the sedative drugs. Propofol was administered intravenously by using the Diprifusor system which is a TCI system using the pharmacokinetic kinetic parameter set according to the Marsh model. The infusion of propofol were controlled under stable BIS target of 60. The administration system is the complex both target control infusion, A2000 BIS monitor (Aspect Medical Newton, Mass) Systems, and PID controller. The blood concentration of propofol at each time point was calculated automatically and shown on the monitor of the TCI pump. For objective measurement and automatically control of consciousness in sedated patients, the close-loop was used. The BIS was kept at 60. Whenever BIS score was changed more than ±10% range of 60 during procedure period, the infusion rate was self-driven adjusted by close-loop controlled computer. 1μg/kg fentanyl was injected as an analgesic agent. All patients were spontaneous breath with oxygen (2 L/min) by nasal cannula during sedation and were kept in the prone position. When adverse event (SBP <80 mmHg or Spo2 <90%) occurred, the solution was an immediate increase in the intravenous fluid infusion or oxygen flow. If hypoxaemia occurred during the sedation, chin lift on the patient and increased the oxygen dose was performed.

Pulse rate, blood pressure, electrocardiogram, and SpO2 were monitored continuously during the procedure. The record of blood pressure was intermittent by 5 minutes. Major data are about hypoxaemia (Spo2<90%) and hypotension (SBP<80 mmHg), and the total propofol dose were recorded during the ERCP.

Statistical Analysis

Continuous variables are presented as the median and range or inter-quartile range (IQR). Comparison of continuous variables was performed by the Mann-Whitney U test, and comparison of dichotomous variables was made by using the Fisher exact test and logistic regression. To extract significant factors for each of major adverse events concerning propofol sedation (hypotension or hypoxaemia). The significance level was set at P<0.05. The resultant data were evaluated by using JMP software version 11 (SAS Institute, Cary, NC)

Results

There were no statistically differences between groups in gender, body mass index, procedure time (see table 1).
The initial target concentration was respectively 2.6μg/mL, 2.1μg/mL and 1.6μg/mL for the three groups. The older patient needed lower sedation concentration at the beginning of ERCP procedure. The total amount of propofol was lowest for oldest patient in the third group (see Table 1).

In addition, there were no significant differences among groups in the percentages of Spo2. Hypo-tension (as defined by SBP<80 mm Hg) tended to occur at higher incidence in the younger groups, but the difference was not significant (group A: 35.6%; group B: 28.5%; group C: 23.3%, P=0.072). Only 4 patients needed vasopressor drugs, such as ephedrine, dopamine or nor-adrenaline to recover from hypo-tension. Hypoxaemia occurred significantly more often in the oldest group, but the prevalence was low (group A: 0%; group B: 2.6%; group C: 5.5%, P=0.001). All patients recovered from hypoxaemia within 30 seconds with chin-lift maneuver, and no patient needed mask assistant breath or tracheal intubation. In addition, no patients has dramatically body-movement. (see Table 1).

Table 1. Characteristics of procedures and adverse events.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Group A (50-70year)</th>
<th>Group B (71-80year)</th>
<th>Group C (&gt;80year)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI (kg/m²)</td>
<td>22.4(20.5-24.4)</td>
<td>22.8(21.0-25.0)</td>
<td>22.5(20.7-24.8)</td>
<td>0.076</td>
</tr>
<tr>
<td>Procedure time (min)</td>
<td>43.5(34.8-72.3)</td>
<td>48.0(38.0-88.2)</td>
<td>46.0(37.6-90.4)</td>
<td>0.093</td>
</tr>
<tr>
<td>Minimum concentration of propofol (µg/mL)</td>
<td>1.8(1.4-2.0)</td>
<td>1.6(1.2-1.8)</td>
<td>1.3(1.0-1.7)</td>
<td>&lt;0.003</td>
</tr>
<tr>
<td>Maximum concentration of propofol (µg/mL)</td>
<td>3.3(2.6-3.8)</td>
<td>2.9(2.4-3.6)</td>
<td>2.6(2.0-3.2)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Average concentration of propofol (µg/mL)</td>
<td>2.6(2.2-3.2)</td>
<td>2.1(1.7-2.8)</td>
<td>1.6(1.5-2.5)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Total infusion dose of propofol (mL)</td>
<td>43(30-62)</td>
<td>35(23-48)</td>
<td>30(18-40)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Hypotension incidence (SBP&lt;80mmHg)(%)</td>
<td>35.6</td>
<td>28.5</td>
<td>23.3</td>
<td>0.072</td>
</tr>
<tr>
<td>Hypoxemia incidence (Spo2&lt;90%)(%)</td>
<td>0</td>
<td>2.6</td>
<td>5.5</td>
<td>0.01</td>
</tr>
</tbody>
</table>

Discussion

Deep sedation in endoscopic treatment for older patients are limited [7,8]. This report evaluated the efficacy and safety of the TCI/BIS close-loop sedation system during ERCP for different age period especially for elder ones. According to the result of our research, there was an obvious correlation between median concentration of propofol and age. The older patients was, the lower concentration and dose of propofol with close-loop TCI/BIS infusion system. With regard to adverse events, the proportion of hypo-tension was highest in younger group, whereas the incidence of hypoxaemia was significantly higher in the older groups (both B and C). However, the actual amount of patients with such adverse event was low, that means close-loop TCI/BIS infusion system is safety for minimally invasive surgery such as ERCP. The possible reason for higher incidence of hypoxaemia in group C was that older patients are accompanied with abating of pulmonary function such as chronic obstructive pulmonary disease (COPD). Hypo-tension mostly occurred in the maintenance period because of the sharp decline of procedure stimulate, whereas hypoxaemia occurred in both the induce and maintenance periods of anesthesia in the reason of obstruction of airway and spontaneous breath depression of propofol. Different from open-loop TCI system, the close-loop system based on BIS can fetch anesthesia depth according to BIS monitor and manipulate TCI pumper to infuse anesthetic with PID controller. The system can remove difficulties of manipulation, inconvenience and individual differences, make anesthesia procedure more stable and easy to operation. Propofol sedation in the elderly patients during ERCP with the TCI/BIS close-loop system was equivalent in the respects of safety and effective compared with the younger ones.

Propofol is a commonly used non-barbiturate sedative hypnotic for clinic practice. It has a favorable pharmacokinetic profile as quick onset and short recovery time. The safety and effective of propofol sedation for ordinary gastrointestinal endoscopy in elderly patients has already been reported [9]. In consideration of propofol’s extremely effective and pharmacology potent, the
adhibition of propofol should be cautious regarding to relatively high incidence of dose-dependent hypo-tension and respiratory depression [10]. Once cardiorespiratory inhibition has occurred, it is necessary to provide extra and timely support until propofol is metabolized because there are no antagonists available. Extra man-made management is means to X-ray exposure to anesthesia doctors. To avoid excessive infusion of propofol, we used the BIS monitoring system, which makes objective evaluation of the depth of sedation possible. The BIS value is generally set at 60 during surgical procedures with general anesthesia showed its effectiveness [6]. In the study, there was an inverse correlation between age and the target concentration of propofol to maintain BIS values at 60. As a result, it was possible to maintain stable sedation with a lower amount of propofol for elderly patients than younger ones with a TCI/BIS system. It was shown that elderly patients require a lower amount of propofol to reach similar levels of sedation than younger [11]. This result suggests that strict control of infusion by the TCI pump automatically adjusted by close-loop titration of the individual sedation depth by BIS monitoring could decrease the dose of propofol in elderly patients.

Based on our findings, hypo-tension was frequently happened in the maintenance period, especially for younger patients that needs more propofol. Because of the short-acting characteristics of propofol, almost all patients recovered immediately with decreases in the dose of propofol without using a vasopressor drug. The result might be explained by the more rapid rate of increase in propofol concentrations [12]. The BIS monitoring system was recommended to reduce the incidence of hypoxaemia and hypo-tension for the elderly [13]. It is believed that stability of the sedation state in the older patient groups through close-loop controlled BIS/TCI system and the higher preoperative SBP in the aged groups. Propofol sedation in the elderly patients during ERCP with the TCI/BIS close-loop system was equivalent in the respects of safety and effective compared with the younger ones. TCI/BIS close-loop system is handy and high-efficiency.

References


