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SHORT REPORT

Propofol-based deep sedation for endoscopic retrograde cholangiopancreatography procedure in sick elderly patients in a developing country

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Introduction: The aim of this study was to evaluate and compare the clinical efficacy of propofol-based deep sedation (PBDS) for endoscopic retrograde cholangiopancreatography (ERCP) procedure in sick (American Society of Anesthesiologists [ASA] physical status III–IV) and nonsick (ASA physical status I–II) elderly patients in a teaching hospital in Thailand.

Methods: We undertook a retrospective review of the anesthesia or sedation service records of elderly patients who underwent ERCP procedures from October 2007 to September 2008. All patients were classified into two groups according to the ASA physical status. In group A, the patients had ASA physical status I–II, while in group B, the patients had ASA physical status III–IV. The primary outcome variable of the study was the successful completion of the procedure. The secondary outcome variables were sedation-related adverse events during and immediately after the procedure.

Results: There were 158 elderly patients who underwent ERCP procedure by using PBDS during the study period. Of these, 109 patients were in group A and 49 patients were in group B. There were no significant differences in age, gender, weight, duration of ERCP, indication of procedure, and the mean dose of fentanyl, propofol, and midazolam between the two groups. All patients in both groups successfully completed the procedure except eight patients in group A and three patients in group B ($P = 0.781$). Overall, respiratory and cardiovascular adverse events in both groups were not significantly different. All adverse events were easily treated, with no adverse sequelae.

Conclusion: In the setting of a developing country, PBDS for ERCP procedure in sick elderly patients by trained anesthetic personnel with appropriate monitoring was safe and effective. The clinical efficacy of this technique in sick elderly patients was not different or worse than in nonsick elderly patients. Serious adverse events were rare in our population.

Keywords: deep sedation, endoscopic retrograde cholangiopancreatography, propofol (ERCP), sick, elderly, American Society of Anesthesiologists (ASA), developing country

Introduction

Despite an increase in the number of patients with hepatobiliary tract diseases, surgical treatment is limited along with risky outcomes such as bleeding, infection or improper postoperative pain control. Endoscopic retrograde cholangiopancreatography (ERCP) is an effective treatment with fewer complications, lower cost, and shorter recovery time than surgery especially for biliary tract abnormalities.[1] Many patients requiring ERCP are older, sicker, and have significant comorbidity. ERCP is an invasive procedure requiring both endoscopy and anesthesia/sedation. Anesthesia consultation before the procedure is needed. Fluid and electrolyte disorders should be corrected and any infection treated. Antibiotic prophylaxis is recommended due to the infection risks.

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In practice, most ERCP procedures are performed in the endoscopy room, with special precautions. The type of anesthesia used is decided according to the patient's medical condition, the anesthesiologist's preference, and the type of endoscopic intervention. Local anesthesia with mild sedation can be used, but to assure better patient comfort during this complicated procedure, short-term general anesthesia or deep sedation is preferred. In our hospital, the majority of ERCP procedures were performed under deep sedation.[2,3]

We conducted a retrospective study to evaluate and to compare the clinical efficacy of the propofol-based deep sedation (PBDS) technique for ERCP procedure in nonsick (American Society of Anesthesiologists [ASA] physical status I, II) and sick (ASA physical status III, IV) elderly patients in a tertiary-care teaching hospital in Thailand. The aim of our study was to confirm that in the setting of a developing country, PBDS for ERCP procedure in sick elderly patients by trained anesthetic personnel was safe and effective and was not different or worse than in nonsick elderly patients.

Methods

Patients

The elderly patients who underwent ERCP procedure at Siriraj GI Endoscopy Center, Faculty of Medicine, Siriraj Hospital, between October 2007 and September 2008 were enrolled in the present study. Inclusion criteria were the elderly patients (age ≥60 years) who underwent ERCP procedure by using PBDS technique. ERCP procedures performed in operating rooms (ORs) and the procedures performed without sedation, or procedures performed under monitored anesthesia care and general anesthesia were excluded.

Study design

This study was a retrospective descriptive study. All elderly patients were classified into two groups according to their ASA physical status. In group A, the patients had ASA physical status I–II. In group B, the patients had ASA physical status III–IV. The primary outcome variable of the study was the successful completion of the procedure. A failed procedure was defined as a procedure that could not be completed by using the PBDS technique when under deep sedation or when sedation-related serious adverse events, such as severe hypoxemia (oxygen saturation [SpO_2] <85% for longer than 3 minutes, which cannot be relieved by airway management) or severe cardiorespiratory instability occur. The secondary outcome variables were sedation-related adverse events during and immediately after the procedure.

Endoscopy procedure

All ERCP procedures were carried out using an Olympus® Video Duodenoscope (TJF 160 R; Olympus Corporation, Tokyo, Japan). The success rate in both groups was recorded. The successful completion of the procedure was defined as completion of the procedure as intended without additional general anesthesia once the procedure had started. After completion of the procedure, admission into the inpatient hospital service was arranged to rule out post-ERCP complications.

Sedation-related procedure

The patients were monitored with noninvasive blood pressure, electrocardiogram (ECG) and pulse oximetry. End-tidal carbon dioxide ($ETCO_2$) monitoring with capnography was not used during sedation. All patients received oxygen supplementation via an oxygen canula (3 L/minute). All procedures were done by using the PBDS technique and all patients were deeply sedated, according to guidelines of the ASA.[4] When, the procedure was a failure, general anesthesia with endotracheal tube was carried out. Sedative/analgesic agents used in both groups were propofol, fentanyl, and midazolam. The dose of sedative and analgesic agents was assessed.

Sedation-related adverse events

All sedation-related adverse events were recorded. Sedation-related adverse events were defined as follows: hypertension or hypotension (increase or decrease in blood pressure by 20% from baseline); tachycardia or bradycardia (increase or decrease in heart rate by 20% from baseline); any cardiac arrhythmias; hypoxia (oxygen desaturation, $SpO_2 < 90\%$); airway obstruction.

Statistical analysis

Results were expressed as mean ± standard deviation (SD) or percentage (%), when appropriate. Comparisons between group A and B were compared by using χ^2 tests (for categorical variables), χ^2 square tests for trend (for ordinal variables), and two-sample independent *t*-test (for continuous variables). The statistical software package SPSS for Windows (v 11; SPSS, Inc, Chicago, IL) was used to analyze the data. All statistical comparisons were made at the two-sided 5% level of significance.

Results

Four hundred and eighty-two patients who underwent ERCP procedures during the study period were enrolled in the study. After matching age, gender, indication of procedure, as well as type of anesthetic technique and type of sedative agent,

there were 158 elderly patients who underwent ERCP by using PBDS. Of these, 109 patients had ASA physical status I–II (Group A) and 49 patients had ASA physical status III–IV (Group B). There were no statistically significant differences in age, gender, weight, and procedure time and indications between the two groups (Table 1).

All PBDS was given by the anesthetic personnel directly supervised by a staff anesthesiologist physically present in the endoscopy room. All sedated patients were deeply sedated, according to guideline of the ASA.[4] Anesthetic personnel included residents in the anesthesiology residency program and anesthetic nurses who are well trained in general anesthesia, intravenous sedation, airway management including intubation, and cardiopulmonary resuscitation. Cardiovascular monitoring, including blood pressure measurements, ECG, heart and respiratory rate, and SpO_2, was performed. $ETCO_2$ monitoring was not used during deep sedation. No premedications were used before the procedure. All patients in both groups were oxygenated with 100% O_2 via a nasal canula.

Table 2 shows the success rate and sedative/analgesic agents used in the sick and nonsick groups. All patients in both groups were concluded with successful completion of the procedure except for eight patients in group A and three patients in group B ($P = 0.781$). All failed procedures were successfully completed by using general anesthesia with endotracheal tube. The combination of fentanyl, propofol, and midazolam was used and there was no statistically significant difference in the mean doses of fentanyl, propofol, and midazolam between the two groups.

Table 1 Characteristics of patients, duration of procedure, and indications of procedure

	Group A (n = 109)	Group B (n = 49)	*P*-value
Age (year) (mean, SD)	63.3 (15.0)	75.1 (9.6)	0.211
Gender (n, %): Male	52 (47.7)	25 (52.0)	0.700
Female	57 (52.3)	24 (49.0)	
Weight (kg) (mean, SD)	56.1 (11.3)	55.4 (10.8)	0.427
ASA physical status (n, %)			<0001*
I–II	109 (100.0)	0	
III–IV	0	49 (100.0)	
Duration of procedure (minutes) (mean, SD)	35.7 (19.3)	38.5 (25.3)	0.063
Indications (n, %)			0.665
Cholelithiasis	59 (54.1)	23 (47.0)	
Hepatobiliary tract tumor	31 (28.5)	17 (34.7)	
Biliary tract stricture	11 (10.1)	5 (10.2)	
Others	8 (7.3)	3 (6.1)	

Notes: Group A: ASA physical status I–II; Group B: ASA physical status III–IV.
*Considered to be statistically significant.
Abbreviations: ASA, American Society of Anesthesiologists; SD, standard deviation.

Table 2 Success rate and sedative/analgesic agents used in both groups

	Group A (n = 109)	Group B (n = 49)	*P*-value
Success rate (n, %)	101 (92.7)	46 (93.9)	0.781
Sedative/analgesic agents (mean, SD)			
Fentanyl			
mg/kg	0.001 (0.000)	0.001 (0.000)	0.717
mg/kg/h	0.002 (0.001)	0.002 (0.001)	0.139
Propofol			
mg/kg	3.87 (2.47)	3.20 (1.94)	0.210
mg/kg/h	7.00 (3.84)	5.89 (3.40)	0.100
Midazolam			
mg/kg	0.03 (0.01)	0.02 (0.01)	0.297
mg/kg/h	0.06 (0.05)	0.05 (0.04)	0.167

Notes: Group A: ASA physical status I–II; Group B: ASA physical status III–IV.
Abbreviation: SD, standard deviation.

Table 3 lists sedation-related adverse events. Overall, 29 patients (26.6%) in group A and 14 patients (28.6%) in group B experienced adverse events. There were no significant differences in overall, respiratory and cardiovascular-related adverse events between the two groups. There were no procedure-related complications in either group.

Discussion

ERCP is an essential procedure among pancreatobiliary tract abnormality treatments, even in our institution where we have observed an increase in the number of these procedures every year. Therefore, it is mandatory to standardize a safe, easy, well-tolerated anesthesiological procedure which is feasible in the gastrointestinal (GI) endoscopy unit. In our experience, we have noted that topical anesthesia alone is not sufficient for pain-free procedures. In contrast, general anesthesia, which may be of benefit for the patient and endoscopist comfort, may be difficult to administer, especially in comorbid patients. Additionally, the lack of experience in anesthesia

Table 3 Sedation-related adverse events (n, %)

	Group A (n = 109)	Group B (n = 49)	*P*-value
Overall	29 (26.6)	14 (28.6)	0.797
Respiratory	6 (5.5)	2 (4.1)	0.706
Hypoxia (SpO_2 < 90%)	2 (1.8)	1 (2.0)	0.930
Upper airway obstruction	4 (3.7)	1 (2.0)	0.589
Cardiovascular	23 (21.1)	12 (24.5)	0.635
Hypotension	20 (18.3)	12 (24.5)	0.374
Bradycardia	3 (2.8)	0	0.241

Notes: Group A: ASA physical status I–II; Group B: ASA physical status III–IV.
Abbreviation: SpO_2, oxygen saturation.

care among endoscopy personnel might increase the risk of complications.

In our hospital, we normally use deep sedation because of the above given reasons in conjunction with the preference of anesthesiologists.[2] Our GI Endoscopy Center has few $ETCO_2$ monitors, and therefore $ETCO_2$ monitoring is not routinely used during deep sedation for GI endoscopy procedures. Consequently, there are no special anesthetic techniques needed for this kind of anesthesia. Cardiopulmonary and other diseases that are more frequent in older and sicker patients have been regarded as the major risk factors for complications associated with endoscopy or sedation.[5–7] Old age and high ASA physical status as important risk factors for endoscopy did not represent indications for providing general anesthesia more frequently for ERCP at our institution. However, the anesthetic technique depends on the experience of the anesthesiologists themselves.

Propofol, combined with short-acting benzodiazepine, with or without fentanyl, has already been used in several GI endoscopic procedures. In this study, we have shown that PBDS with low-dose midazolam and fentanyl, and low-dose propofol, is safe and well tolerated by the patient. Furthermore, it is well accepted by endoscopists. No patients enrolled in the study needed to be resuscitated during ERCP procedure. All patients could be discharged to the ward within 60 minutes from the end of this procedure, and this discharge time was not correlated with age, ASA physical status, or total sedative doses.[8]

Patients were breathing spontaneously; however, SpO_2 was always over 95%, and age, ASA physical status, and the combination of sedative agents did not negatively influence this parameter. Also, heart rate was only partially affected. Sedation is performed to ensure the patient's safety, to minimize physical discomfort or pain, to provide analgesia and procedural amnesia, to control behavior during the procedure and to return the patient to their pretreatment level of consciousness. Propofol is widely employed for anesthesia outside the OR because it is easy to use, has a good safety and efficacy profile due to its quick onset of action, rapid metabolism, significantly shorter recovery time, and has some anti-emetic effects.[9–11] All of these properties are useful in endoscopic procedures.

Propofol is known to decrease blood pressure in young and old individuals.[10] This effect was noticed in this study. However, severe hypotension requiring resuscitation treatments did not develop for increasing age, or ASA physical status groups. The influence of age on propofol dose in decreasing systolic blood pressure has already been described.[12] In addition, propofol-based sedation did not increase the complication rate.[6,13]

Low-dose of midazolam combined with low-dose fentanyl and propofol did not prolong recovery time. Consequently, sick patients (ASA physical status III–IV) may be sedated utilizing this combination technique. However, the combined group studied was small, and more patients are therefore needed.

The present study used only standard monitoring, including an assessment of blood pressure, pulse rate, respiratory rate and pulse oximetry, as well as electrocardiogram. We detected a relatively high overall rate of adverse events in both groups. This rate is higher than that commonly reported, and there may be several explanations. We used these criteria in defining adverse events: hypo/hypertension and brady/tachycardia measured as the changes of blood pressure and heart rate of more than 20% of baseline values. Hypoxia was defined as $SpO_2 < 90\%$. Hypercapnia ($ETCO_2 > 50$ mm Hg) could not be detected directly in this study. Moreover, if only serious adverse events are included, the adverse event rate is only 1.8% in the nonsick group and 2.0% in the sick group, which corresponds to previously published studies.[14] Moreover, if only serious adverse events are included, the adverse event rate is only 1.8% in the nonsick group and 2.0% in the sick group.

In one cohort study, 1000 patients undergoing endoscopic ultrasonography procedure were sedated with propofol for deep sedation and received meperidine and midazolam for moderate sedation. There did not appear to be a significant difference between complication rates for deep sedation and for moderate sedation. There were no serious adverse events.[15] We believe that the appropriate selection of patients for sedation is very important for everyday practice and will most likely reduce the rate of adverse events. Finally, the use of pulse oximetry to monitor hypoxemia is important, especially in cases when supplemental oxygen is administered. At our institution, most procedures are performed in the prone position. The present study demonstrates that ERCP can be effectively performed in this position with the patients under deep sedation.

Data from our previous study showed that both patient and endoscopist satisfaction in sedated patients was higher than in nonsedated patients. The use of sedation was the major determinant of patient satisfaction and willingness to repeat.[16] However, deep sedation contributed to an increased recovery room time. Among all of these benefits, it is advantageous to identify the particular factors that might encourage patients to undergo ERCP procedure with deep sedation. Moreover, the present study showed that ERCP procedure in sick elderly patients can be performed safely and effectively with

a lower complication rate under PBDS technique. We think that low-dose fentanyl combined with low-dose midazolam and low-dose propofol is the ideal combination for PBDS. In our hospital, intravenous sedation is extensively used for GI endoscopy procedures in geriatric patients.[17] However, this is not widespread in the district community hospital.

This study has a few limitations. First, there is the wide range in age of the patients in our study. Drug requirements, recovery time, and side effects can be related to patient's age. Second, inaccurate and incomplete documentation of certain measures, as occurs with many chart reviews, also occurred in this study. Third, the limitation of monitoring, such as of $ETCO_2$, could result in a lower rate of adverse events. Finally, different anesthesiologists define complications differently. Overall, despite these limitations, we are, however, confident that these findings are generalizable to the practice of ERCP procedure using deep sedation. Finally, because the rate of serious complications in our series was low, further studies in larger prospective groups of patients are therefore needed.

Conclusion

We report the performance of the clinical efficacy of PBDS regimen utilizing anesthetic personnel with appropriate basic monitoring for ERCP procedure in sick, elderly patients in a unit outside the OR from a tertiary-care teaching hospital in a developing country. The findings of the present study showed that the ERCP procedure done by PBDS technique for sick, elderly patients was safe and effective, and its efficacy was not different or worse than in nonsick elderly patients. The combination of low-dose fentanyl, midazolam, and propofol may be beneficial.

Disclosure

The authors report no conflicts of interest in this work.

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