

Registered nurse-administered sedation for gastrointestinal endoscopic procedure

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Abstract

The rising use of nonanesthesiologist-administered sedation for gastrointestinal endoscopy has clinical significances. Most endoscopic patients require some forms of sedation and/or anesthesia. The goals of this sedation are to guard the patient's safety, mini-

mize physical discomfort, to control behavior and to diminish psychological responses. Generally, moderate sedation for these procedures has been offered by the non-anesthesiologist by using benzodiazepines and/or opioids. Anesthesiologists and non-anesthesiologist personnel will need to work together for these challenges and for safety of the patients. The sedation training courses including clinical skills and knowledge are necessary for the registered nurses to facilitate the patient safety and the successful procedure. However, appropriate patient selection and preparation, adequate monitoring and regular training will ensure that the use of nurse-administered sedation is a feasible and safe technique for gastrointestinal endoscopic procedures.

Key words: Registered nurse; Sedation; Gastrointestinal endoscopy; Safety; Complication

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Core tip: The registered nurse-administered sedation for gastrointestinal endoscopy (GIE) procedures has clinical consequences. Generally, moderate (conscious) sedation for these procedures has been offered by the registered nurses by using benzodiazepines and/or opioids. Sedation training courses including clinical skills and knowledge are necessary for the registered nurses to facilitate the patient safety and the successful procedure. However, appropriate patient selection and preparation, adequate monitoring and regular training as well as anesthesiologist consultation in high risk cases and procedures will ensure the use of sedation by registered nurses is a safe and effective technique in GIE procedure.

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INTRODUCTION

Currently, gastrointestinal endoscopy (GIE) procedure is usually performed for diagnosis and treatment of gastrointestinal abnormalities. The need for sedation is depended on the patient physical status, degree of endoscopic difficulty and type of endoscopy, duration of procedure and physicians' preferences. The best methods for sedation during these GIE procedures are still controversial^[1]. Endoscopic sedation can be administered by the trained nurse. However, the nurse administering sedation must be skilled to manage the oversedated patients^[2,3]. The aim of the report is to present the current knowledge and the clinical application for routine clinical practice concerning the registered nurse-administered sedation for GIE procedures.

DEFINITIONS

Several guidelines created by the American Society of Anesthesiologists (ASA)^[4] and the American Academy of Pediatrics^[5] created the guidelines and definitions of procedural sedation.

Minimal (mild) sedation

Patient generally responds to the verbal command. Cardiorespiratory functions are unchanged. Minimal sedation does not invoke the monitoring requirements define in this policy. Although minimal sedation does not technically characterize the procedural sedation, the physicians should be aware that sedation can readily develop to the deeper level of sedation depth. The physicians and the registered nurses should be prepared to appropriately care for the patient in the event the level of sedation deepens.

Moderate (conscious) sedation

Patient responds persistently to the verbal command or light tactile stimulation. Additionally, the interventions are not needed to maintain the patent airway and the cardiorespiratory functions are sufficient and also usually preserved.

Deep sedation

Patient responds persistently to repeated or painful stimulation. The capacity to preserve respiratory function may be diminished. In addition, the patient may necessitate support in maintaining the airway and spontaneous respiration may be insufficient. However, the cardiovascular function is generally preserved.

General anesthesia

Patient does not response to the painful stimulus. The cardiorespiratory functions are usually reduced and the patients commonly demand the support in maintaining the airway. In addition, the positive pressure ventilations may be needed.

INDICATIONS

The two primary goals of suitable sedation for GIE procedures are to assist the procedures, and to reduce the anxiety and discomfort^[6]. The optimal depth of sedation levels that registered nurses should be aiming for is minimal or moderate sedation depth^[7].

LOCATIONS

Currently, endoscopic sedation can be performed in many units. The majority of practical locations of GIE procedures are endoscopy unit and operating room. Physicians who can facilitate the use of GIE sedation include the registered nurses, gastroenterologists, surgeon and anesthesiologists^[8].

REQUIREMENTS

Personnel

A physician who continues current advanced life support qualification and who is familiar with endoscopic sedation, must be immediately available during the sedation and after the procedure. Resident and trainee may contribute in the GIE procedures by the supervision of staff physician. The physician is responsible for prescribing the medications including dose and type as well as also understanding pharmacology and the complications related with the sedative drugs. The physician will be in attendance throughout the procedure and will be responsible for managing the patient and must be able to manage the complications that may occur. In addition, the physicians performing the GIE procedure will maintain the responsibility and the competency for providing GIE sedation.

Consequently, an extra person is needed to establish an airway management. The registered nurses with appropriate competency can administer sedative medications with a written physician's order^[9]. In addition, the registered nurse must be continuously monitored the patient and must be skilled to recognize clinical signs of hypoventilation and respiratory depression as well as abnormal vital signs and pulse oximetry readings. Importantly, the physician performing a GIE procedure can not be the person monitoring the patient.

Procedure room

The endoscopic room must be large sufficient to contain the operative personnel and monitoring equipments as well as permit an emergency cart to be brought into the room for emergency patient resuscitation. Additionally, the endoscopic room has adequate power outlets and adequate lighting to observe the patient and the monitoring equipments. The cart system with adequate space for the monitors, placed in a position where it is easily visible at all times for the personnel performing the procedural sedation.

Resuscitation equipment

The oxygen source, face mask and bag as well as suction equipments will be available in the endoscopic room. These equipments should be functional and checked before the start of GIE procedure. Moreover, the airway equipments including laryngoscope, endotracheal tubes and airways as well as an emergency cart will be available for the urgent use. This emergency cart must include the equipments for administering the resuscitate drugs and intravenous fluids including blood and blood components, as needed^[1].

Monitoring

The patient undergoing sedation will be continuously monitored by the registered nurse with appropriate competency and knowledge. Consequently, vital signs, oxygen saturation and the responsiveness to a verbal stimulus will be documented before administration of sedative medications, 5 min during the endoscopic procedure and at least every 15 min in the recovery room. Electrocardiogram should be established in the high risk patients including elderly patients, patients with cardiac problems and ASA physical status \geq III^[1].

PRE-SEDATION ASSESSMENT

Pre-procedural assessment and preparation part is very important. All patients scheduled for GIE sedation will have a pre-procedural assessment by a physician or registered nurse that includes the patient's medical condition, allergies, previous experience with sedation, drug use, alcohol and tobacco use, past medical history and current medications. A goal of physical exam including airway assessment and the major organ systems will be carried out. ASA physical classes of the patients should be documented before the procedure. A high ASA physical class is at increased risk for developing complications during sedation. Appropriate pre-procedure consultation with the proper specialists including an anesthesiologist is strongly recommended for the patients with severe underlying diseases.

The physician and the registered nurses are responsible for determining and documenting the patient's ASA physical class. If the provider determines that the patient is in an unstable condition or the GIE procedure is more invasive or complicated, sedation should not be considered by the registered nurses and an anesthesiologist consultation is recommended. Furthermore, the patients with ASA physical status IV or V are not the suitable cases in the absence of an anesthesiologist. Routine laboratory testing should not be carried out. However, the laboratory testing ought to depend on patients' physical status and underlying diseases.

Moreover, the informed consent must be completed before sedation is administered or the procedure is performed. All patients will be counseled on the risks, benefits, limitations and methods of sedation and also documented in the medical record before giving

sedative drugs. Importantly, the patients can not drive home after sedation. A responsible adult person who will transport the patient should be confirmed before starting the GIE procedure. Fasting should be adhered to the guidelines except for necessary medications. All adult patients should be fasting for at least six hours before the procedural sedation. However, patients with normal gastric emptying time may have clear liquids in moderate amounts three hours prior to sedation. In addition, a time-out will be accomplished before the endoscopic procedure.

AMERICAN SOCIETY OF ASA CLASSIFICATION

The patient physical status is assessed from the ASA classification system. The ASA class should be determined by a person who will be performed GIE sedation: (1) ASA I: Healthy patients; (2) ASA II: Minimal systemic diseases, controlled on medications such as controlled hypertension, diabetes; (3) ASA III: Severe systemic diseases with some limitations such as asthma, heavy smoking, obesity or multiple severe systemic illnesses all well controlled on medications, the patient with history of myocardial infarction or cerebrovascular accident; (4) ASA IV: Severe systemic diseases with severe limitations and life threatening such as poorly controlled hypertension, diabetes and coronary arterial disease; and (5) ASA V: Not predicted to live 24 h regardless of any intervention.

PREPARATION OF SEDATION

The registered nurse who administered the sedative drugs should be considered monitoring equipments and availability of emergency medications and equipments during preparation of the procedure. The registered nurse may take the responsibility to monitor the patient during and after GIE sedation. In addition, the intravenous line must be continued all through the GIE sedation.

SUPPLEMENTAL OXYGEN

Several guidelines advise that oxygen supplementation should be performed during moderate and deep sedation^[4]. However, oxygen supplementation will delay the finding of apnea by the pulse oximetry. The capnography can be a role for monitoring ventilation. Clinically, the incidence of desaturation will be reduced during the oxygen supplementation^[10].

INTRAPROCEDURAL MANAGEMENT

Monitoring equipments during intraprocedural period should be included pulse oximetry, blood pressure monitor and ECG monitor. Resuscitation equipments and the reversal agents could be immediately accessed. Consequently, patients should receive supplemental

oxygen during the procedure when oxygen saturation reduces a 3% below their baseline saturation. An airway evaluation of the patient is continuously assessed. All evaluation and documentations are also noted. Accordingly, the consciousness should be reviewed frequently whenever sedative drugs are being titrated as well as also documented during sedation. Importantly, the patient is still remained responsive to a verbal stimulus and continued sufficient spontaneous ventilation. Ventilation should be continuously observed by clinical assessment. In patients where verbal response is not possible, search for other indications of consciousness.

A registered nurse experienced in moderate sedation can monitor and sedate the ASA physical status I-II patients. Generally, anesthesiologist should be consulted for the ASA physical status IV-V patients and the deeply sedated patients as well as the high-risk patients. These patients need special care to make certain adequacy of pulmonary ventilation and to maintain hemodynamic parameters. In addition, the patient's airway must be supported and maintained.

SEDATIVES AND ANALGESIAS

Benzodiazepines

Benzodiazepines are widely used in procedural sedation even in GIE sedation because of their anxiolytic effects and dose-dependent anterograde amnesia^[11]. Diazepam is not an ideal agent for short GIE procedures and in the outpatient cases because of its very long elimination half-life. In contrast, midazolam is the commonest premedication and sedative agent because of its pharmacokinetic properties^[11]. Midazolam has a synergistic effect with anesthetic drugs. In that way, it can reduce the sedative medications^[12]. Respiratory depression is the most important side effect of benzodiazepines when used in combination with opioids and/or sedative drugs. The standard dose is 0.03-0.1 mg/kg intravenously. The registered nurse can be safely used these drugs for GIE sedation.

Opioids

Opioids are usually used for the reduction of procedural pain and positional discomfort. Opioids are often used and carefully titrated with the combination of other sedative drugs^[11]. The choice of which opioid should be used significantly depends on patients' physical status, the type and the duration of endoscopic procedure. Fentanyl and pethidine are widely used for GIE procedures. Similar to benzodiazepines, the registered nurses can be safely used the opioids for GIE sedation.

Pethidine

Pethidine (meperidine) is a synthetic opioid. Its onset and duration of action is longer than fentanyl. The standard dose of pethidine is 0.5-2 mg/kg intravenously. Its use in the renal insufficiency patients increases the potential for neurotoxicity. The patients taking

monoamine oxidase inhibitors are contraindicated with pethidine^[13]. Pethidine is commonly combined with midazolam for GIE procedure in the adult patients^[14,15]. Pethidine and fentanyl are equally effective in providing analgesia for pediatric GIE procedures^[16,17].

Fentanyl

Fentanyl has a rapid and short duration of action. It is also a synthetic opioid, and is the commonest opioid used for GIE sedation^[11]. Normally, the dose of fentanyl is 0.5-2 mcg/kg intravenously. A previous study demonstrated that there were no significant differences in the recovery period, patient satisfaction, time to awake and sedation-related cardiorespiratory complications between the fentanyl-based sedation and the alfentanil-based sedation for esophagogastroduodenoscopy and colonoscopy. However, fentanyl is cheaper than alfentanil in each case^[18].

Sufentanil

Sufentanil is also a synthetic opioid and is more potent than fentanyl. The standard dose of sufentanil is 0.1 mcg/kg intravenously^[19]. Few studies have been evaluated the clinical efficacy of sufentanil in GIE procedure. In a previous study, the authors compared analgesia and sedation provided by one of four different opioids in combination with midazolam during GIE procedure. Patients were given 1-3 mg midazolam and sufentanil 5-10 mcg, meperidine 50-100 mg, fentanyl 50-100 mcg or alfentanil 150-300 mcg plus additional opioid and/or midazolam if needed. The study was concluded that sedation and analgesia were comparable in the upper gastrointestinal groups. Recovery time was shorter with sufentanil and alfentanil. However, analgesic properties of meperidine were significantly greater than sufentanil^[20].

Alfentanil

Alfentanil also has a rapid and short duration of action. However, it is less potent than fentanyl. Donnelly and colleague studied the efficacy and cost of substituting sedation by using alfentanil and midazolam for the existing regimen of diazepam and meperidine in patients underwent upper GIE procedure. Their study demonstrated that the use of alfentanil for sedation in upper GIE procedure was safe and effective, and did not increase the total sedation cost^[21]. Moreover, Liu *et al*^[22] colleague demonstrated that the patient controlled analgesia with propofol and alfentanil offered greater sedation and patient satisfaction as well as a low complication rate compared with the combination of opioid and benzodiazepine.

Remifentanil

Remifentanil has an ultra-short action. It is a synthetic opioid. Importantly, the clearance of remifentanil is unchanged in the patients with hepatic and renal impairment^[11,23]. Generally, remifentanil is given only by a continuous infusion technique. An analgesic dose of

remifentanyl is 0.025-0.15 mcg/kg per min^[24]. However, remifentanyl is not extensively used for GIE procedure. Further studies should to be investigated.

REVERSAL AGENTS

Naloxone

Naloxone is an opioid antagonist. A dose ranges from 1-4 mcg/kg intravenously, and it may be repeated if required. The duration of action of naloxone is about 30-45 min^[11]. Because of its short duration of action, an infusion dose of 3-5 mcg/kg per hour could be used after a bolus dose.

Flumazenil

Flumazenil is a benzodiazepine antagonist. It selectively binds to the GABAA receptor complex. The duration of action is approximately 1 h. The standard dose of flumazenil is 0.2 mg intravenously. It can be repeated if necessary. The maximum dose of flumazenil is 1 mg/dose and 3 mg/h^[11]. Similar to naloxone, flumazenil can cause acute withdrawal syndrome in the patients who receive benzodiazepines chronically^[11].

SAFETY OF NURSE-ADMINISTERED BENZODIAZEPINES AND OPIOIDS

Generally, the registered nurses can administer the benzodiazepines and opioids for moderate sedation in GIE procedures. Additionally, the registered nurse also can be administered the reversal agents by the order of a physician^[25]. Consequently, the study of Yang *et al*^[26] also investigated the nurse-administered moderate sedation by using the clinical criteria (Ramsay sedation scale, RSS) compared with using Bispectral Index values. They used midazolam and fentanyl or hydromorphone. The authors confirmed that the registered nurses could be safely and effectively performed moderate sedation by using benzodiazepine and opioid for GIE procedures.

However, the registered nurses should not to be sedated in the advanced GIE procedures such as ERCP and EUS procedures^[27]. Guimaraes and colleagues assessed a cohort study of 9598 patients underwent ERCP and EUS procedures. The incidence of sedation and endoscopy-related complications as well as serious morbidity and mortality rates were compared. The study demonstrated that the anesthetic management for ERCP and EUS procedures in high-risk patients significantly decreased the incidence of sedation-related complications when compared with the registered-nurse care. However, endoscopy-related complications were unchanged^[27].

PROPOFOL

Propofol is a phenol derivative with rapid and short duration of action. It has anxiolytic, hypnotic, anesthetic

and antiemetic properties. The onset of action is about 30-60 s. The plasma half-life ranges from 1 to 4 min^[28]. However, it does not have an analgesic effect. Propofol is commonly used for sedation in therapeutic GIE procedures^[15]. It also potentiates the effects of other sedative drugs. The disadvantages of propofol are related with airway obstruction, apnea and hypotension as well as pain at the injection site.

NURSE-ADMINISTERED PROPOFOL

To date, propofol administration by nonanesthesiologists is controversial. Advocates of nurse-administered propofol sedation are due to the patient safety and the low cost^[3,29,30]. American Society of Anesthesiologists guideline on sedation by nonanesthesiologists describes propofol as an anesthetic agent that is commonly related with deep sedation^[4]. The use of propofol for routine GIE procedures also is not recommended by American Society of Gastrointestinal Endoscopy^[31]. Generally, the registered nurses administered propofol sedation is cost-effective.

Several studies have been demonstrated the safety and efficacy of the registered nurses administered propofol sedation. For example, the study of Rex *et al*^[32] demonstrated that the registered nurses and endoscopists could safely administer the propofol for GIE endoscopy^[32]. Additionally, several data were also confirmed these in the invasive GIE procedures including ERCP, EUS and balloon endoscopy^[33,34].

Moreover, the safety of nurse-administered propofol sedation in an ambulatory center also confirmed by the report of Walker and colleagues^[35]. This report described the authors' experience in 9152 GIE procedures. The sedation-related adverse events were observed in seven patients including laryngospasm, apnea and pulmonary aspiration and all related with upper GIE procedures. However, tracheal intubation was not needed in all these cases.

To date, no clinical studies are directly compared between the registered nurse and gastroenterologist or endoscopist-administered sedation for GIE procedures. The administration of propofol by registered nurse is usually performed under direct supervision of the physician. The safety profiles of this sedation technique by the registered nurse for GIE procedures were evaluated in 27500 patients. Among these patients, 6.7% developed hypoxemia (SpO₂ < 90%) and 6.2% required oxygen supplementation. Severe hypoxemia (SpO₂ < 85%) was observed in 0.62% and 0.25% during upper GIE and colonoscopy, respectively. Bag mask ventilation or tracheal intubation was not required. Hypotension was observed in 1.2% and 3.5% during upper GIE and colonoscopy, respectively, and was immediately treated by using intravenous fluid administration. The mean recovery time was 14.6 min. This study demonstrated that propofol administration by the registered nurse was safe and effective^[36].

Several studies have been confirmed that gastro-

enterologist or endoscopist can be safely and effectively performed GIE sedation in mild or moderate depth of sedation level. Redondo-Cerezo and colleagues assessed the efficacy and safety of endoscopist-administered propofol for GIE procedures^[37]. They studied the propofol administration by gastroenterologist for sedation in EUS procedure. The induction time, duration of procedure, recovery time, patients' comfort and safety, hemodynamic profiles and complications as well as patient and endoscopist satisfaction were analyzed. Their study confirmed that propofol administration by gastroenterologist for EUS procedure in the elderly or the high-risk populations was safe and effective^[38].

Recently, a tool for evaluation of the competency of the registered nurse-administered propofol has been developed by Jensen *et al*^[39]. The study explored the reliability and validity of the nurse-administered propofol assessment tool. This study demonstrated that the assessment of sedation proficiencies could be performed by using a simulator. However, the video assessment required experienced physicians. Overall, this assessment tool demonstrated a good validity. Further investigations and controlled studies need to be confirmed.

POST-SEDATION CARE

Following the procedure, the registered nurse must continually monitor the patient until the patient ready to discharge. The patient also remains the responsibility of the registered nurse during the recovery period. Generally, the institutions would establish the recovery and discharge criteria for their patients. The recovery unit must have proper monitoring and resuscitation equipments.

The patients' vital parameters and the level of consciousness should be continuously observed in the post-sedation unit. The registered nurse is also required to manage the complications in this unit. The intravenous line and monitors should be utilized until the patient meets specific discharge criteria. If the reversal agents are used, the patients ought to be observed for ≥ 90 min after the administration of these drugs to assure they do not become re-sedated.

DISCHARGE CRITERIA

The registered nurses working in the post-procedural care use the discharge scoring system to assess the patient before discharge home or move to the ward. The discharge scoring systems such as the Aldrete score and the Post-Anesthesia Discharge Scoring System (PADSS) are commonly used for GIE procedures. The Aldrete and the PADSS scoring systems need continuous re-assessment of the patient. However, all discharge scoring systems have some disadvantages^[40]. Importantly, the high-risk patients should be individually assessed. Currently, the reliability of these discharge scoring systems is clearly demonstrated. In the

ambulatory setting, patients now accept the idea of going home only a few hours after diagnostic and/or therapeutic GIE procedures. The content and delivery of discharge instructions that outpatients receive from the registered nurse is very important. So far, the role of the registered nurse in providing patient education at the discharge process is becoming increasingly^[41].

Importantly, the discharge criteria must be present before a patient can be discharged following GIE sedation. The following criteria suitable for the discharge are patient oriented to time, place and person or at pre-procedure status, vital signs within 20%-30% of pre-procedure values, unobstructed airway and sufficient ventilation, adequate oxygenation, easily and appropriately responsive to verbal commands, no severe pain and nausea/vomiting as well as the Aldrete score should be 9 or 10 in a total of 10. In the author's previous study, the periodic assessment of the home-readiness showed that most patients would complete an acceptable score on or before 1 h after GIE procedure. The time to complete an acceptable score associated with the type of GIE procedures. Consequently, most delayed recovery times after acceptable recovery scores were owing to the non-medical causes^[42].

ANESTHESIOLOGIST CONSULTATION

The majority of sedation-related complications during and after GIE procedures are respiratory-related events such as pulmonary aspiration, hypoventilation, airway obstruction and apnea as well as the cardiovascular-related events such as hypotension and bradycardia^[43]. Sedation-related adverse events are a risk to the success of the GIE procedure itself. Endoscopic sedation training is a very important issue. The registered nurses can learn about GIE sedation when to call for help and when to join the services of anesthesiologists. To date, the registered nurse should consult anesthesiologists for the patients with ASA physical status IV and V and the patients with known or suspected difficult airway management. In addition, anesthesiologists should be required for emergency or complicated GIE procedures such as ERCP, EUS and small bowel enteroscopy^[44]. Moreover, anesthesiologist consultation is advocated for the patients with extremes of age or with significant renal or liver impairment, severe cardiorespiratory diseases, history of difficulty with moderate sedation, patients with previous inadequate response or adverse effect to moderate sedation, alcohol and drug abuse as well as patient or procedure needed at least deep sedation depth.

CONCLUSION

The use of registered nurse-administered sedation for GIE procedures has clinical significances. Most endoscopic patients require some forms of sedation and/or anesthesia. Generally, mild and moderate sedation for GIE procedures has been offered by the

nonanesthesiologist by using benzodiazepines and/or opioids. In contrast, the propofol sedation by the registered nurse is depended on the knowledge, skills and experience of individual nurse as well as the policy and the country guidelines. Importantly, the sedation training courses including clinical skills and knowledge as well as anesthesiologist consultation in high risk cases and procedures are necessary for the registered nurses to facilitate the patient safety and the successful GIE procedure. Additionally, appropriate patient selection and preparation, adequate monitoring and regular training will ensure that the use of registered nurse-administered sedation is also a practicable and safe technique for GIE procedures.

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