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ORIGINAL ARTICLE

Safety of Nonanesthesiologist-administered Propofol Sedation in Endoscopic Ultrasound

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ABSTRACT

Background: Sedation during complex endoscopic procedures is important for comfort and safety of patient and ensures smooth and efficient completion of the procedure. This article evaluates safety of nonanesthesiologist-administered propofol (NAAP) sedation during endoscopic ultrasound.

Materials and methods: Patients undergoing endoscopic ultrasound (EUS) with propofol sedation at Center for Liver and Digestive diseases (CLD), Holy Family Hospital, Rawalpindi, Pakistan were included. The primary outcome variable was the frequency of any sedation-related complication.

Results: One hundred and ten patients fulfilling the inclusion criteria were enrolled in the study. Sixty (54.5%) patients were male and 50 (45.5%) were females. The mean age of study patients was 49 ± 18 years. The mean propofol dose was 203 ± 119 mg. There were 41% (n = 45) in ASA class I, 40% (n = 44) in ASA class II and 19% (n = 21) in ASA class III. The most common endosonographic finding was mediastinal and/or abdominal lymphadenopathy (30.9%, n = 34) followed by a pancreatic mass in 21.8% (n = 24) patients, and a space occupying lesion (SOL) in liver in 15.5% (n = 16) patients. There were three cases with gallbladder mass (2.7%), two cases with CBD mass (1.8%), three cases (2.7%) with esophageal growth and 10 (9.1%) cases with gastric masses. Most of the patients, i.e. 98.2% (n = 108) had no sedation-related complication. Only 1.8% (n = 2) patients developed sedation-related minor complications who only required bag mask ventilation and subsequently recovered without any sequel.

Conclusion: NAAP for endoscopic sedation is safe in patients undergoing EUS.

Keywords: Safety, Propofol, Nonanesthesiologists, Endoscopic ultrasound.

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INTRODUCTION

Upper endoscopic ultrasound (EUS) is principally used for diagnosing and staging gastroenterological and pancreatic tumors. The procedure requires deeper level of sedation than simple endoscopic procedures owing to the larger diameter (13 mm) and long (2-3.5 cm), rigid distal tip of a EUS scope. The addition of EUS-guided fine needle aspiration (FNA) frequently makes the procedure more complex and time consuming.[1]

Propofol is a short-acting sedative and hypnotic that probably acts on the gamma-aminobutyric acid in the central nervous system. It is increasingly being used for sedation during routine endoscopic procedures.[2] A significant number of endoscopists from United States of America use conventional sedation. The reason for reluctance to use propofol is due to widespread perception of an increase complication risks and medicolegal concerns.[3,4] These concerns are mainly due to a FDA-approved product label, which limits administration of propofol sedation to trained and certified anesthesiologists.[5]

The concept of nonanesthesiologist-administered propofol (NAAP) for gastrointestinal (GI) endoscopy has been endorsed by four major gastroenterology societies in the United States.[6] NAAP has been provided additional evidence by a recently published worldwide safety survey of 646,080 procedures with endoscopist-directed propofol sedation.[7] Gastroenterology trainees in US are now also being advised to develop additional expertize in endoscopic sedation during gastroenterology fellowship.[8]

The main rationale of our study is to document and validate the safety of propofol sedation by nonanesthesiologists in EUS at our center. To the best of our knowledge this will be the first study on this topic in our country. If the safety of propofol sedation is validated, it will open new horizons of endoscopic sedation and enhance the confidence of gastroenterologists across the country to use propofol and conduct similar studies at their centers. This will help us to develop local consensus guidelines for endoscopic sedation in accordance with the international guidelines.

MATERIALS AND METHODS

All patients who underwent EUS with propofol sedation by trained nurses at Center for Liver and Digestive Diseases (CLD), Holy Family Hospital, Rawalpindi, Pakistan were consecutively enrolled in the study. The study period was between October 2011 and March 2012. The enrolled patients were required to be in American Society of Anesthesiologists (ASA) class I, II and III. The exclusion criteria were (1) patients in ASA class IV, V, (2) patient age < 18 years, (3) pregnant women, (4) inability to provide informed consent, (5) patients with known respiratory disease, (6) patients with neurologic impairment, (7) patients with known allergy to the drugs used, (8) patients suffering from obstructive sleep apnea, (9) history of seizure disorder, (10) short neck, inability to adequate mouth opening and history of difficult intubation.[9]

All the procedures were performed in left lateral with a mouthpiece in place. Intravenous access was established with an 18 to 20 gauge cannula in the right forearm. During the procedure 1,000 cc of saline solution was infused as continuous infusion through a 3-way connector. An initial bolus of 0.5 mg/kg body weight of propofol was infused, followed by boluses of 0.05 mg/kg mg as required for conscious sedation.[10] Oxygen was given via nasal prongs at the rate of 2 to 3 L/min. Patients were monitored continuously by a monitor for oxygen saturation (alarm if the oxygen saturation fell below 90), heart rate (alarm if the heart rate declined to less than 60 beats/minute or exceeded 110 beats/minute). The assisting nonanesthesiologist monitored chest movements, breathing patterns, depth of sedation and level of pain. Full resuscitation equipment was available within the endoscopy unit at all times.

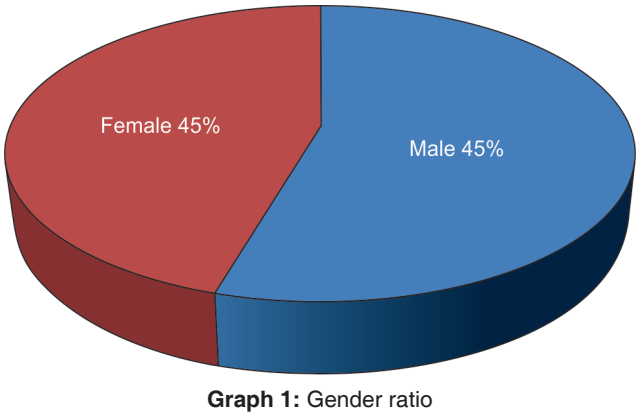
All the data was retrospectively collected after seeking permission from the ethical committee of the hospital. Informed consent of the concerned patients was taken for their records to be used in this study. It included Medical Record (MR) no, age, gender, ASA class, mean dosage and presence or absence of sedation-related complication (both minor and major).

The complications were entered as (1) absent, (2) minor complications, i.e. requiring bag mask ventilation (either directly or via an endotracheal tube) with subsequent recovery at the place of procedure, (3) major complication, i.e. needing cardiopulmonary resuscitation and shifting to intensive care and or death.

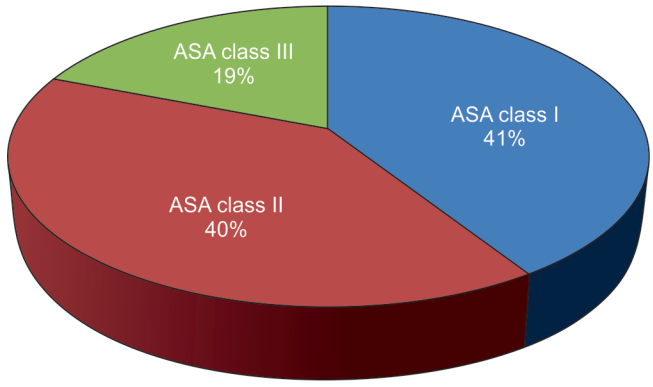
SPSS version 17.0 was used to analyze the data. Mean of quantitative variables like age and frequency and percentages of variables like gender, EUS findings and complications will be calculated. A p value ≤ 0.05 was regarded as statistically significant.

RESULTS

One hundred and ten patients fulfilling the inclusion criteria were enrolled in the study. Sixty (54.5%) patients were male and 50 (45.5%) patients were female (Graph 1). The mean age of study patients was 49 ± 18 years. The mean propofol dose used was 203 ± 119 mg. There were 41% (n = 45) patients in ASA class I, 40% (n = 44) patients in ASA class II and 19% (n = 21) patients in ASA class III (Graph 2).



Graph 1: Gender ratio



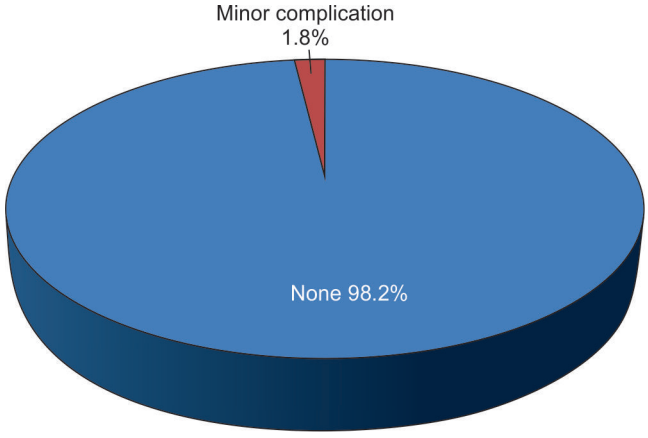
Graph 2: Distribution of patients according to ASA classification

The most common endosonographic finding was mediastinal and/or abdominal lymphadenopathy (30.9%, n = 34) followed by pancreatic mass (21.8%, n = 24), and SOL liver (15.5%, n = 16). There were three cases of gallbladder mass (2.7%) and two cases of CBD mass (1.8%), three cases (2.7%) of esophageal growth and 10 (9.1%) cases of gastric masses. Miscellaneous findings consist of pancreatic and renal cysts, liver and renal cyst, periampullary mass, hydatid cyst, a mass behind mesenteric artery, subdiaphragmatic collection and cirrhotic liver (Table 1).

Table 1: Frequencies of EUS findings

EUS findings	*No. of patients (%)*
Mediastinal lymphadenopathy	17 (15.5%)
Abdominal lymphadenopathy	09 (8.2%)
Abdominal lymphadenopathy + mediastinal lymphadenopathy	3 (2.7%)
Mediastinal mass	5 (4.5%)
Esophageal growth	3 (2.7%)
Gastric mass/wall thickening	10 (9.1%)
SOL liver	16 (14.5%)
Gallbladder mass	3 (2.7%)
CBD mass	2 (1.8%)
Pancreatic masses	20 (18.2%)
Chronic pancreatitis	4 (3.6%)
Miscellaneous	9 (8.2%)
NAD	9 (8.2%)

Most of the patients, i.e. 98.2% (n = 108) had no sedation-related complication. Only 1.8% (n = 2) patients developed sedation-related minor complications (Graph 3). All of them required bag mask ventilation and recovered without any sequel. There were no major complication in the form of requirement of endotracheal intubation and shifting to intensive care unit for mechanical ventilation. There were no sedation-related deaths.



Graph 3: Sedation-related complication

DISCUSSION

Propofol is extensively used by anesthesiologists and gastroenterologists for endoscopic sedation.[9] Assisted ventilation and or orotracheal intubation is seldom required for simple upper GI endoscopies and colonoscopies, when performed under propofol sedation.[12,13] The American Society of Gastrointestinal Endoscopy (ASGE) fully supports the concept of NAAPs. The NAAP must be skilled in advanced cardiac life support.[11] The airway management is particularly important for patients undergoing oxygen desaturation. Laryngeal mask could be the rescue procedure of choice in patients who do not respond to bag mask ventilation.[14,15]

The frequency of minor complications in our study (1.8%) is quite comparable to other studies. A multicenter study of 36,743 patients evaluated the role of NAAPs for simple and advanced upper endoscopic procedures. According to the results of this study, the percentage of patients requiring assisted ventilation during propofol sedation by NAAPs was 0.1 to 0.2%.[2] Similarly, in a recent study evaluating balanced propofol sedation (BPS) during EUS-FNAC, minor respiratory adverse events and assisted ventilation occurred in seven patients (6.3%) and three patients (2.7%) respectively.[15] In an another study by Yusoff et al, no patient required assisted ventilation during NAAP sedation in EUS, although a minority of patients (1%) developed minor hypoxemia ($SpO_2 < 90\%$) which responded well to an increase in flow rate of supplemental oxygen.[16]

A high incidence of propofol related adverse respiratory events during GI endoscopy has also been mentioned in literature (Dewitt et al: 51%[17] and Fatima et al: 21%).[18] The reason for this apparent conflict is due to different criteria adopted for defining sedation-related complications. In our study, as previously mentioned (see Materials and Methods), minor sedation-related complications were defined as those requiring positive pressure ventilation via bag mask or endotracheal tube with subsequent recovery in the endoscopic suite and major complication were those which in addition to above, resulted in shifting of patient to intensive care unit, those requiring cardiac resuscitation and or resulted in death of patient. The transient change in heart rate from baseline and decrease in oxygen saturation were monitored and documented but not included in the definition of sedation-related adverse events due to following reasons:

1. The transient changes in heart rate and oxygen saturation responded well to simple basic maneuvers like increasing the flow rate of intravenous fluids or supplemental oxygen.
2. These transient events never progressed to more serious sedation-related adverse events, as to be included in the minor or major sedation-related complication according to definition of our study.
3. Although there is no doubt regarding the monitoring and documentation of these parameters, including these minor fluctuation as defining criteria for sedation-related complication will result in the documentation of a high percentage of sedation-related adverse effects. This will raise doubts in the section of gastroenterologists who are still reluctant to use propofol for endoscopic sedation in the absence of a certified anesthetic.

The percentage of patients developing major complications with NAAP also varies in the literature. In our study no patient developed major complication in the form of tracheal intubation and requiring mechanical ventilation and/or death. In the study of use of BPS in EUS-FNAC (mentioned above) only one patient developed prolonged hypoxia which required use of laryngeal mask airway. That particular procedure was subsequently terminated.[15] In another study on the use of propofol sedation with monitored anesthesia care (MAC), Nayyer et al mention an overall complication rate of 0.6% (6/1,000 patients). Out of these six patients, three patients required endotracheal tube placement but still the procedures were completed. The patients were extubated after the procedure and discharged the same day.[19]

There are two important observations from Nayar et al. First, the sedation-related complication rate with the anesthesiologists is almost comparable with nonanesthesiologists. Second, the requirement of orotracheal intubation and subsequent removal was not regarded as a major sedation-related complication. By following the above definitions of sedation-related adverse events, a much lower major complications with propofol sedation will be documented and published in the literature which will surely lessen a lot of anxiety associated with propofol use.

CONCLUSION

Propofol sedation in EUS by nonanesthesiologists appears to be a safe option provided the person responsible for sedation

should be trained in advanced cardiac life support. Future studies in this regard are required with the possibility of a multicenter trial in future which will enable us to develop a consensus guideline, both at national and international level.

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