Clinical Study

Balanced Propofol Sedation in Patients Undergoing EUS-FNA: A Pilot Study to Assess Feasibility and Safety

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Introduction and aims. Balanced propofol sedation (BPS) administered by gastroenterologists has gained popularity in endoscopic procedures. Few studies exist about the safety of this approach during endosonography with fine needle aspiration (EUS-FNA). We assessed the safety of BPS in EUS-FNA.

Materials and methods. 112 consecutive patients, referred to our unit to perform EUS-FNA, from February 2008 to December 2009, were sedated with BPS. A second gastroenterologist administered the drugs and monitored the patient.

Results. All the 112 patients (62 males, mean age 58.35) completed the examination. The mean dose of midazolam and propofol was, respectively, of 2.1 mg (range 1–4 mg) and 350 mg (range 180–400). All patients received oxygen with a mean flux of 4 liter/minute (range 2–6 liters/minute). The mean recovery time after procedure was 25 minutes (range 18–45 minutes). No major complications related to sedation were registered during all procedures. The oxygen saturation of all patients never reduced to less than 85%. Blood systolic pressure during and after the procedure never reduced to less than 100 mmHg.

Conclusions. In our experience BPS administered by non-anaesthesiologists provided safe and successful sedation in patients undergoing EUS-FNA.

1. Background

Propofol is a short-acting sedative, agonist of \( \gamma \)-aminobutyric acid receptor in the central nervous system [1]. Its use has principally been limited to anesthesiologists for the induction and maintenance of deep sedation in patients undergoing surgical procedures. Recently propofol use has extended to sedation in endoscopic procedure, administered by anesthesiologists or by gastroenterologists [2].

Propofol administered by nonanesthesiologists has shown to be safe for an upper endoscopy, a colonoscopy, and advanced endoscopic procedures, such as an ERCP and an EUS [3]. For endoscopic procedures the use of midazolam, with or without meperidine, in combination with propofol is called balanced propofol sedation (BPS). It has been shown that BPS compared to propofol alone decreases total propofol doses required and increases patient comfort [4–6].

2. Aim of the Study

The purpose of this preliminary study was to assess safety and feasibility of gastroenterologist-administered BPS for operative upper EUS in a tertiary referral center with a previously established program for colonoscopy sedation with propofol.

3. Patients and Methods

The study received approval from our institutional review board. From February 2008 to December 2009 patients who presented at our unit for an operative EUS were eligible for the study if they were age 18 years or older, American Society of Anesthesiology (ASA) class I or II, and capable to provide written informed consent for study participation. Exclusion criteria were inability to provide informed consent, history of...
more than 20 seconds, use of supplemental oxygen (O2) by nasal cannula (NC) in excess of 4 L/min, positive pressure ventilation (PPV) or laryngeal mask use, hypotension, bradycardia. EUS was used by an experienced endosonographer who had practiced for 2 years after completing a therapeutic endoscopy fellowship and performed over 500 EUS procedures yearly. The echoendoscope was inserted once the patient was responsive only to mild prodding and the tongue was flaccid to manual palpation. EUS-guided FNA (EUS-FNA) was carried out in a standard fashion by using a 22-gauge needle. After the procedure, the patients were transported to the recovery room where blood pressure, \( \text{SpO}_2 \), and heart rate were measured continuously until discharge. Discharge was possible when Glasgow Coma Scale score of the patient was >9 and OSSA scale was 5 (see Table 2).

### 4. Results

Between February 2008 and December 2009, 253 consecutive patients were considered for enrollment. Among these, 53 patients were excluded because their ASA class was III, 34 patients were excluded because their Mallampati score was more than 2, 10 because of a history of sleep apnea syndrome, 44 patients refused to provide informed consent to participate in the study. Overall 112 patients were included in the study. Demographic and baseline characteristics of the patients are shown in Table 1, as well as indications for EUS-FNA. The most common indication was the evaluation of a known or suspected pancreatic mass or cyst. The mean dose of propofol given was 350 mg (range 180–400 mg), and the mean dose of midazolam was 2.1 mg (range 1–4 mg). All patients received supplemental oxygen in nasal cannula at the mean flux of 5 L/min. The mean procedure time in our study was 42.96 ± 15 min. A mean of 3 passes of EUS-FNA was performed (range 2–5). The accuracy of EUS-FNA was 75.3%. One endoscopic complication occurred (0.9%), a perforation of the duodenal bulb in a patient with a pseudodiverticulum of the bulb subsequent to an ulcer. After an attempt of conservative management with the positioning of a nasogastric drainage, total parenteral nutrition and intravenous antibiotic therapy the patient was referred to the surgical unit because of peritonism. The patient is doing well after 3 months of followup. In 5 patients (4.5%) the blood pressure reduced to less than 90 mmHg during an interval of time between two measurements (10 minutes). Administering fluids allowed a rapid increase of the blood pressure above the target value. In 3 patients (2.7%) the heart rate decreased to less than 50 pulses per minute for more than 1 minute. With the administration of intravenous buscopan, the heart rate rose back to more than 50 pulses per minute in few seconds in all these patients. In 5 patients (4.5%) oxygen saturation decreased to less than 90% while they were receiving oxygen with a 4 L/min flux. Two patients rapidly recovered increasing in the flux to 8 L/min, two patients needed mask ventilation for few minutes with complete recovery of a normal blood oxygenation, but this event required the stop of the procedure that was completed with anesthesiological assistance. In one patient (0.9%) the insertion of a laryngeal mask was necessary for a desaturation episode, with an oxygen saturation value of less than 85% lasted more than 3 minutes despite mask ventilation. In this case the procedure was definitively stopped without performing FNA. In all the other patients the blood pressure never decreased under 90 mmHg, the heart rate never reduced to less than 50 pulses per minute and the oxygen saturation (SaO2) from the baseline were recorded. The baseline values and changes in vital signs or manifestations of restlessness or discomfort. The maximum dose allowed to be administered was 400 mg.

### Table 1: Baseline population characteristics.

| Parameter                                 | Value            |
|-------------------------------------------|------------------|
| Age, median years (range)                 | 58 (25–86)       |
| Male/female                               | 62/50            |
| ASA grade                                 |                  |
| Class I                                   | 68               |
| Class II                                  | 34               |
| Indication for FNA                        |                  |
| Mediastinal nodes                         | 26               |
| Submucosal lesion                         | 14               |
| Pancreatic mass                           | 72               |
| Needle passes (range)                     | 3 (2–5)          |
| Baseline hemodynamics, median (range)     |                  |
| Mean blood pressure mmHg                  | 125 (85–168)     |
| Pulse, per minute                         | 71 (48–90)       |
| SaO2, %                                   | 96 (94–100)      |

ASA, American Society of Anesthesiologists’ grade.
and faster discharge postprocedure \[10–12\]. Several studies titration of propofol to moderate sedation \[13\]. This regimen (BPS) enhances the sedative e

also known as “balanced propofol sedation” (BPS) and the variables associated with complications from its use for EUS have been also described \[20\]. In the paper of Fatima et al., by using univariate analysis, patient age, propofol dose, procedure length, and EUS-FNA were not associated with the risk of any sedation-related complications \[21\].

In our center there has been a strong interest in propofol sedation in the last 4 years, in particular for colonoscopy sedation. Since 2006, our staff has performed more than 5000 colonoscopies with BPS. Nevertheless, features of EUS and, in particular, EUS-FNA procedure features are consistently different from colonoscopy. EUS-FNA is a difficult and time-consuming procedure. Upper endoscopic procedure are at higher risk of respiratory complications as reported in the literature \[22\]. Beside this, EUS instruments have a major caliber compared to gastroscopes. An EUS-FNA procedure lasts more than a gastroscopy or a colonoscopy and, for safety reasons, during FNA a deeper level of sedation is often required.

The current study was designed to assess the feasibility and the safety of EUS-FNA performed with BPS sedation administered by gastroenterologists. The administration of propofol by gastroenterologist may be not as cost-effective as when it is administered by trained nurses, but, at present, it is the only way allowed in our institution. During the study, an anaesthesiologist was on call in case of adverse events. The anaesthesiologist was free of other duties attending only to nonclinical activities and ready to reach the endoscopic suite in few minutes.

In our series we found no major complications. All but one procedures were completed. Minor adverse events occurred in 7 patients (6.3%) and were easily treated. Overall, 5 patients (4.5%) had a decline in SBP <90 mm Hg. All episodes of hypotension were treated by increasing the rate of IV fluids. The episodes of hypotension did not require discontinuation of the procedure. The mean procedure time in our study was 42.96 ±15 min, not different from reported data \[23\]. In the current series, we found a decrease in \(\text{SpO}_2\) < 25% in 5 patients (4.5%), rapidly responsive to supplemental \(\text{O}_2\) administration in 2 patients; 3 patients (2.7%) required assisted ventilation. One procedure (0.9%) was not completed due to prolonged hypoxia treated by laryngeal mask positioning.

### Table 2: Observer’s scale for sedation and alertness (OSSA) score.

| Score | Responsiveness | Eyes                      |
|-------|----------------|---------------------------|
| 5     | Responds readily to name | Clear and no ptosis         |
| 4     | Lethargic response to name | Glazed or mild ptosis (less than half of eye) |
| 3     | Responds only when called loudly or repeatedly | Marked ptosis (more than half of eye) |
| 2     | Respond after mild prodding or shaking |                           |
| 1     | Unresponsive to mild prodding or shaking |                           |

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In our experience BPS can be a safe protocol of sedation for healthy patients undergoing EUS-FNA. Comparing our data to the literature there seems to be a difference in minor complication rate. In particular we experienced the need for mask ventilation in 3 patients, in one case with the use of laryngeal mask. We also had in our series one perforation (0.9%). This observational study was not designed to assess the difference of complication between different protocols of sedation, but comparing data to an historical cohort of patients that underwent EUS-FNA with anaesthesiological assistance a similar rate of minor complication was found. In particular a perforation of the duodenal bulb was reported in the cases with anaesthesiological assistance. The diagnostic yield of FNA in this series is similar to the literature data. The major concern of propofol sedation is the respiratory depression. The results of our series stress the importance of the training in the airway management of the staff involved in BPS. Laryngeal mask use, in particular, should be considered mandatory for the gastroenterologists administering this kind of sedation.

In conclusion, our experience suggest a good profile of safety of BPS administered by gastroenterologist in EUS-FNA procedures. According to our results no significant increase in the procedure-related complication rate was registered and the diagnostic yield of FNA performed with this protocol of sedation is not different from the literature data. Gastroenterologist administering propofol for EUS-FNA must be skilled in advanced life support, with particular regard to airway management. Laryngeal mask, having a shorter learning curve than orotracheal intubation, could be the rescue procedure of choice in patients undergoing oxygen desaturation nonresponsive to mask ventilation.

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