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Original article

Optimizing Sedation for Upper GI Endoscopy: Propofol *versus*Midazolam: A Clinical Study at Sirte Oncology Central

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ABSTRACT

Keywords: Upper gastrointestinal endoscopy, Propofol, Midazolam, Sedation, Recovery time, Oxygen saturation.

Upper gastrointestinal (GI) endoscopy is a common diagnostic and therapeutic procedure, typically performed under conscious sedation to improve patient comfort and cooperation. However, the choice of sedative remains a topic of ongoing debate. This study aimed to compare the safety and efficacy of midazolam and propofol for sedation during upper GI endoscopy. A total of 80 patients scheduled for elective upper GI endoscopy at the Endoscopy Unit of our hospital between February 2023 and October 2023 were recruited for this prospective, randomized controlled trial. Patients were randomly assigned to two equal groups: one group received propofol, while the other received midazolam. The anesthesiologist was aware of the sedative agent being administered, but the patients were blinded to the treatment. Both sedatives were administered via intravenous bolus, with dosages adjusted as needed to maintain an appropriate level of sedation. The recovery time was significantly shorter in the propofol group compared to the midazolam group. While the propofol group exhibited a decrease in systolic blood pressure, this was transient and did not result in significant adverse effects. In contrast, the midazolam group experienced a notable reduction in oxygen saturation, with a higher incidence of hypoxia compared to the propofol group. No major adverse events, such as cardiac arrhythmias or respiratory depression, were observed in either group during the procedure. The sedation quality, as assessed by the Observer's Assessment of Alertness and Sedation (OAA/S) scale, was stable throughout the procedure in the propofol group, while some variability was noted in the midazolam group. The results of this study suggest that propofol is a more effective and safer sedative agent than midazolam for upper GI endoscopy. Propofol offers faster recovery times and more stable sedation, with fewer complications related to oxygen saturation. It is therefore recommended as the sedative of choice for upper GI endoscopy, although careful monitoring of blood pressure is essential.

Introduction

Upper gastrointestinal (GI) endoscopy is a vital and widely utilized diagnostic and therapeutic procedure in the management of various upper GI conditions such as peptic ulcers, gastric varices, tumors, and gastrointestinal bleeding. This minimally invasive procedure provides essential visual insights that guide clinical decision-making. Although endoscopy is considered minimally invasive, the process typically requires sedation to ensure patient comfort, minimize distress, and facilitate optimal procedural conditions. Furthermore, appropriate sedation enhances the patient's cooperation and tolerance, reduces procedural discomfort, and minimizes the risk of complications, ensuring a quicker return to baseline mental and physical states after the procedure, which is particularly valuable in outpatient settings [1,2]. Sedation for endoscopy procedures is typically classified into four levels: minimal, moderate, deep, and general anesthesia [3]. The goal in most upper GI endoscopies is moderate sedation, also referred to as conscious sedation. Moderate sedation allows the patient to remain responsive and able to follow commands while still being relaxed and free of discomfort. Conscious sedation can help reduce anxiety and pain, enabling the procedure to be performed with minimal distress. It also minimizes the risk of patient movement, which could interfere with the procedure [3].

However, sedation levels must be carefully monitored and controlled, as deeper levels of sedation than intended may significantly increase the risk of adverse events. For example, deeper sedation can lead to hypoxia, where oxygen levels in the blood become dangerously low, increasing the risk of respiratory distress or even apnea. Additionally, deeper sedation increases the likelihood of cardiovascular instability, such as hypotension or arrhythmias, which could complicate the procedure and delay recovery [4,5]. As such, it is essential to balance the depth of sedation to ensure both procedural success and patient safety. Benzodiazepines, and in particular midazolam, remain among the most commonly used sedative agents for conscious sedation in upper GI endoscopy. Midazolam's advantages include its ability to produce anxiolysis, short-term amnesia, and muscle relaxation, all of which are beneficial during the procedure. Its relatively short half-life is another reason for its popularity, as it allows for a quicker return to baseline cognitive function post-procedure [6]. Despite these benefits, midazolam has limitations. Achieving a



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stable and predictable sedation level with intermittent intravenous bolus administration can be challenging, leading to periods of over-sedation or under-sedation [7]. Over-sedation, in particular, may result in prolonged recovery times and an increased risk of complications such as hypoventilation.

In response to these limitations, propofol, a short-acting intravenous hypnotic agent, has gained significant popularity in recent years for upper GI endoscopy. Propofol has a rapid onset of action and a short duration of effect, allowing for smoother induction and quicker recovery after the procedure. Additionally, propofol provides better patient satisfaction and more stable procedural conditions compared to midazolam, especially for patients undergoing more complex endoscopic procedures [8]. However, its use is not without risks. Due to its narrow therapeutic window, propofol can cause serious side effects, such as hypotension, respiratory depression, and apnea, particularly when administered too quickly or in excessive doses. These side effects are a critical consideration when using propofol for sedation in clinical practice, as they necessitate close monitoring of the patient throughout the procedure [1,2].

Recent studies and meta-analyses have suggested that propofol may be more effective than midazolam in certain populations, especially in patients with cirrhosis, where liver function may affect drug metabolism [11]. Propofol has also been shown to be beneficial in reducing the incidence of side effects such as nausea and vomiting post-procedure, a common issue with midazolam [12]. However, given the risks associated with propofol, particularly respiratory depression and the need for precise dosing, its use is often restricted to settings where anesthesia personnel or experienced endoscopists can closely monitor the patient during and after the procedure. This practice is in line with guidelines that recommend the use of propofol for sedation only in institutions equipped to manage its potential complications.

In addition to midazolam and propofol, another sedative agent, dexmedetomidine, has emerged as a potential alternative for moderate sedation in upper GI endoscopy. Dexmedetomidine, an a2-adrenergic agonist, offers the benefit of minimal respiratory depression, a significant advantage over agents like propofol. Its sedative effects are characterized by a cooperative, calm patient who remains easily arousable and capable of responding to commands. However, like other sedatives, dexmedetomidine is not without risks. It can lead to bradycardia and hypotension, which can be problematic in patients with underlying cardiac conditions [13]. Moreover, dexmedetomidine is not yet as widely used as propofol or midazolam, primarily due to its cost and the specialized monitoring it requires.

As the body of research on sedation continues to evolve, it is clear that no single sedative agent is ideal for all patients or all endoscopic procedures. The choice of sedative should take into account various factors, including the patient's comorbidities, the complexity of the procedure, and institutional resources. Guidelines and protocols for sedation in upper GI endoscopy have been developed to standardize practices, minimize complications, and improve overall outcomes [7]. It is essential that sedation practices are tailored to individual patient needs and procedural requirements to ensure safety and success.

Methods

This was a prospective, single-blind, randomized controlled trial conducted between February 2023 and October 2023 at the Gastrointestinal Endoscopy Unit of Sirte Oncology Central, SIRT University, Sirte, Libya. The study involved 80 patients scheduled to undergo upper gastrointestinal endoscopy. Participants were randomly divided into two groups: 40 patients received propofol for sedation, and 40 patients received midazolam (8). The inclusion criteria involve patients aged > 20 years and classified as ASA I or II (American Society of Anesthesiologists physical status classification) [1]. On the other hand, patients classified as ASA III or VI or those with a history of allergy to the drugs used or pregnant were excluded [2]. Sedation protocol provided sedation using intravenous bolus doses of the two drugs as follows.

Midazolam Group

Initial dose: 3-5 mg.

Maintenance dose: 0.5–1 mg every 2-3 minutes, with a maximum cumulative dose of 10 mg or 0.1 mg/kg body weight [8].

Propofol Group

Initial dose: 0.5 mg/kg.

Maintenance dose: 10-20 mg bolus as needed to maintain the desired level of sedation [7].

All patients underwent a thorough clinical history and physical examination before the procedure. Baseline vital signs, including blood pressure, heart rate, respiratory rate, and oxygen saturation, were recorded and continuously monitored throughout the procedure. To evaluate the level of sedation, the Observer's Assessment of Alertness and Sedation (OAA/S) scale was used. The OAA/S score was recorded every two minutes during the procedure. In addition, continuous monitoring includes oxygen saturation (SpO2), heart rate, blood pressure, and respiratory rate. Cardiopulmonary events, such as hypoxemia



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(defined as SpO2 < 90% for >30 seconds after applying the jaw thrust maneuver), hypotension (≥20% decrease in systolic or diastolic blood pressure), and bradycardia (heart rate <50 bpm), were also closely monitored [8]. Independent observers were responsible for these tasks. If hypoxemia was identified, supplemental oxygen was administered at a rate of 3-4 L/min. If the patient's oxygen saturation improved, hypoxemia was considered mild. In cases where the patient's oxygen saturation did not improve, further interventions such as noninvasive ventilation (e.g., bag-mask ventilation) or intubation were performed [2]. The two groups were compared based on the following outcomes:

Time to induction: The interval between the administration of the first drug bolus and the start of the procedure. Time to recovery: The interval between the removal of the endoscope and the final sedation assessment. Time to discharge: The interval between endoscope removal and the patient's departure from the endoscopy unit.

The final assessment was made when the bispectral index (BIS) monitor indicated a value of at least 90. Patients were considered ready for discharge only after the BIS was > 90, the OAA/S score reached 5 (maximum alertness), and no pain or discomfort was reported [15].

Results

(Table 1) shows that there is no significant difference between the two groups with regard to age. Sex and ASA I, II class. Furthermore, patients in both groups were comparable about patient body mass index, and serum levels of albumin, international normalized ratio [INR], and creatinine (Table 1). Outcomes among the studied patients were presented in detail in (Table 2). Briefly, both propofol and midazolam groups were comparable with regard to endoscopy time, basal systolic blood pressure, basal oxygen saturation, heart rate, and OAA/S throughout the whole procedure. However, recovery time was significantly shorter in the propofol group. On the other side, systolic blood pressure was significantly reduced in the propofol group at midpoint and recovery times, while oxygen saturation was significantly reduced in the midazolam group at an intermediate point of the procedure. Finally, hypoxic events were more widely distributed among the midazolam group [reported in 20.0%], while none in the propofol group. No hypotension or bradycardia was reported in any patients in both groups.

Table 1: Characters of studied patient

Variable		Propofol	Midazolam	Test	P
Age [years]		51.57±4.69; 39-58	51.50	0.11	0.92
ASA	I	22[73.3%]	20	0.31	0.58
	II	8[26.7%]	10	0.31	0.58
Sex	M	20[66.7%]	17	0.64	0.43
	F	10[33.3%]	13	0.64	0.43
Weight [kg]		73.55	72.4	0.59	0.56
Height [m]		1.70	1.63	0.61	0.56
BMI		27.18	26.9	0.42	0.70
ALBUMIN		4.1	4.2	0.06	0.95
Creatinine		0.19	0.83	0.82	0.42
INR		1.15	1.14	0.25	0.81

ASA: American society for anesthesiologists

Table 2: Outcome among studied patients

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Variable	Propofol	Midazolam	Test	P			
Endoscopic time	30.28	31.30	1.50	0.20			
Recovery time	7.54	29.47	22.90	0.001			
SBP	19.18	8.20	10.14	0.001			
HR	2.14	1.81	1.24	0.22			
OAA/S	2.84	2.83	1.03	0.33			
Hypoxia	0	9 (20%)	6.68	0.011			
Spo2	96.68	94.90	2.74	00.8			

SBP: Systolic blood pressure; SPO2: oxygen saturation; HR: heart rate; OAA/S: The Observer's Assessment of Alertness/Sedation

Discussion

The search for the most effective and safest sedative agent for upper gastrointestinal (GI) endoscopy continues, as each drug exhibits a unique safety and efficacy profile. In this study, we compared propofol



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and midazolam for sedation during upper GI endoscopy and found that propofol is superior in terms of both safety and efficacy.

Several studies support the superiority of propofol, highlighting its ability to provide stable sedation throughout the procedure. It is well-documented that patients receiving propofol sedation report fewer instances of restlessness or discomfort compared to those receiving midazolam [11, 12]. The advantages of propofol are numerous, including its rapid onset of action, short duration, and faster recovery time. This allows for continuous infusion, ensuring a consistent depth of sedation, which is critical for both patient comfort and procedural success. However, propofol has a narrow therapeutic range, which can lead to cardiovascular depression if doses are not carefully managed [13]. Combining propofol with synergistic agents can reduce the required dosage, thereby decreasing the risk of cardiovascular dysfunction while maintaining the desired sedation depth [14].

Recent studies further emphasize the safety and effectiveness of propofol for sedation during upper GI endoscopy. Wang et al. [15] demonstrated that propofol is both safe and effective in healthy and cirrhotic patients, offering a quicker recovery and higher patient satisfaction than midazolam. Additionally, propofol sedation was associated with fewer cardiovascular and pulmonary complications, making it an attractive option for a wider range of patients. Similarly, Poulos et al. [16] advocated for the use of propofol, even in cirrhotic patients, due to its shorter recovery times and enhanced patient satisfaction, as well as its reduced incidence of procedure-related discomfort. These findings align with our own results, where propofol showed a faster recovery and a more stable sedation profile.

Correia et al. [17] also reported findings consistent with those of the current study, highlighting the advantages of propofol in terms of both patient recovery and sedation quality. Moreover, Martinez et al. [13] examined the safety of continuous propofol sedation in elderly patients, finding that although geriatric patients are more susceptible to complications, the safety profile of propofol remains favorable when used appropriately.

In a meta-analysis conducted by Singh et al. [18], the recovery time for cirrhotic patients was significantly shorter with propofol sedation compared to midazolam. Additionally, the study highlighted that patients sedated with propofol reported greater satisfaction and comfort during the procedure, despite similar endoscopy times between the two drugs. These findings are consistent with our results, which demonstrate that propofol offers significant benefits over midazolam in terms of patient experience and procedural efficiency. Finally, Watanabe et al. [19] reported that physician satisfaction was notably higher with propofol sedation due to the reduced movement of patients during the procedure. This reduction in patient movement not only enhances procedural success but also decreases operator stress, improving the overall experience for the healthcare team.

Conclusion

Our study demonstrates that propofol is a more effective and safer sedative agent than midazolam for upper gastrointestinal endoscopy. Its rapid onset, consistent sedation, and quick recovery profile make it an ideal choice for this procedure. Given its favorable safety margin, propofol should be considered the sedative of choice, provided that continuous cardiovascular monitoring is maintained—especially during higher doses. Combining propofol with low doses of midazolam or analgesics may enhance sedation quality while minimizing cardiovascular side effects. Proper training of anesthesia providers remains essential to ensure prompt management of potential adverse events such as hypoxia, hypotension, or bradycardia. Further studies comparing propofol with other sedatives, such as dexmedetomidine, are recommended to refine patient-tailored sedation strategies and optimize procedural outcomes.

Conflict of interest. Nil

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