

Midazolam for Conscious Sedation During Endoscopy: Cheaper and Safer Alternative for Resource-poor Settings

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Abstract:

Upper gastrointestinal endoscopy is usually carried out using conscious sedation or general anesthesia all over the world. However, due to resource-poor conditions in countries like Bangladesh, physicians have to use topical anesthesia, which eventually leads to a painful and fearful endoscopic experience for most of the patients here. To improve this situation, a cross-sectional study was carried out in a tertiary medical center near Dhaka, Bangladesh from March 2013 to October 2018. A total of 4557 patients were included in this study. Among them, 2236 patients were sedated with low dose Midazolam in a conscious sedation procedure, while 2321 patients underwent endoscopy with only topical anesthesia using Lidocaine gel and Lidocaine spray. It was found out that patient satisfaction with Midazolam was 99% compared to only 10% with lidocaine use. Besides, only 4% of patients were restless, but did not need anesthetic support, when Midazolam was used. In contrast, 35% of patients with topical anesthesia were found restless and were assisted. Midazolam is certainly a better and cheaper alternative in resource-poor settings and provides a painless, patient-friendly endoscopic experience without the need for anesthetic support.

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Introduction:

Upper gastrointestinal (UGI) endoscopy is an essential diagnostic procedure for different disorders ranging from peptic disorders to UGI cancers. It is used for therapeutic purposes also. For the compliance of the patients and successful completion of a safe examination, adequate patient tolerance is a must during endoscopy. All over the world, endoscopy is done either under conscious sedation or under general anesthesia in presence of anesthesiologists.^{1,2} In accordance with practice standards and social customs, procedural sedation usage varies considerably among different countries. For example, sedation was usually or always administered in 44 percent

of procedures in Asia, 56 percent in Europe, and 72 percent in the Americas according to a survey published in Gastrointestinal Endoscopy.³ But in resource-poor settings like Bangladesh, the cost of the procedure and limited availability of expert anesthesiologists limit the use of standard anesthesia or conscious sedation during endoscopy. This is why the procedure is done using topical anesthesia in most of the centers.

Parameters like successful completion of examinations, patient satisfaction and comfort level, and patients' willingness to undergo future examinations remain good in case of moderate sedation or conscious sedation. It brings about better tolerability, improves general acceptance, and offers a more satisfactory service. In peripheral centers of Bangladesh, topical anesthesia with Lidocaine (Spray and Gel) is usually used. But its use is limited by an unpleasant memory and painful sensation during endoscopy. For this, many patients feel anxious about the procedure and deny to undergo it routinely. During "conscious sedation", patients' cardiovascular (CVS) and respiratory system are voluntarily stabilized with a clear response to stimuli like sound and touch⁴. For conscious sedation, benzodiazepines and opioids

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are used, especially Propofol and Midazolam. Propofol has faster induction and recovery time. But its side effects can cause apnea and hypotension.^{5,6} Furthermore, it requires proper pre-anesthetic checkup and an expert anesthetist during the procedure. These make the sedation technique costlier, as high as triple, in comparison to topical anesthesia use. Midazolam, a benzodiazepine drug used as a sedative, has strong amnestic and ataxic effects. However, it can cause respiratory depression, and its onset of action and recovery time are too long. But this drug can be a useful one in a low resourceful country like Bangladesh for its low cost and longer safety profile as an endoscopic premedication. This paper thus focuses on a cheaper alternative for sedation during endoscopy in terms of patient compliance, safety, and efficacy without the need for an anesthesiologist in resource poor settings.

The objective of our study was to assess the use of a low-cost drug in sedation procedure for diagnostic endoscopy in a resource-poor setting like Bangladesh. Low dose Midazolam is an excellent drug in this perspective with its amnestic and sedative effects. It can reach the highest blood level within 15 minutes and has a short half-life and very few side effects⁷.

Methods:

Patients & Design

This descriptive cross sectional study was carried out in a tertiary medical center near Dhaka, Bangladesh during the five-year period from March 2013 to October 2018. A total of 4557 patients were assessed by diagnostic endoscopy and were included in this study. Written informed consent was taken from all patients. Among them, 2236 patients were sedated with low dose Midazolam (0.06 mg/kg) I/V slowly for conscious sedation procedure. The rest 2321 patients underwent endoscopy with topical anesthesia using both Lidocaine gel (2%) and Lidocaine spray (10%). All patients were assessed prior to endoscopy for CVS and respiratory illness. Patients under 18 years and over 80 years were excluded from the study. All patients underwent proper pre anesthetic checkups. During the procedure, patients were monitored with automated BP recording and O₂ saturation monitoring (by pulse oximetry) until full recovery. Conscious sedation was performed in presence of an endoscopy attendee. For safety reasons, patients were counseled not to drive until 12 hours after the procedure.

The outcome was measured by a questionnaire having four components: a) whether the patient was satisfied with

sedation b) whether the patient could remember the endoscopic insertion c) whether the patient could remember endoscopic withdrawal d) whether the patient felt any pain or unpleasant sensation during the procedure. The information recorded on the questionnaire was based on detail history taking by interviewing the patients and attendees. We also recorded any adverse event that occurred during the procedure like low O₂ saturation level (SpO₂<95%), arrhythmia, restlessness or agitation, delayed or assisted recovery. All the information and data were systemically recorded and analyzed by SPSS version 23 and have been shown in the tabulated form. The quantitative data were expressed in frequency and mean +/- SD and the qualitative data were expressed in frequency and percentage. This study was carried out after obtaining approval of the Ethical review committee.

Results:

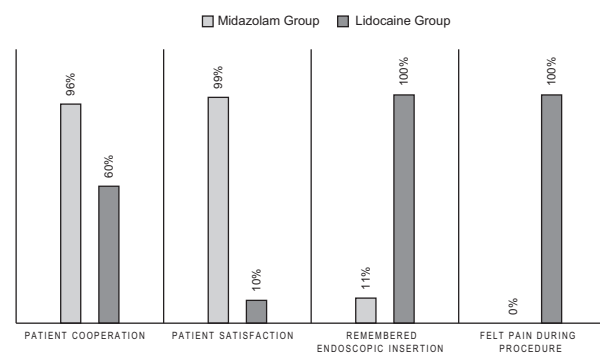
In the first group, a total of 2236 patients were intravenously injected low dose midazolam (0.06%) slowly. Endoscopic insertion was done within 30 seconds of injection. On the other hand, 2321 patients underwent endoscopy with topical anesthesia using both Lidocaine gel (2%) and Lidocaine spray (10%). No significant difference was observed between these two groups in terms of major complications. With Midazolam, patients had a better satisfaction profile than those with topical anesthetics. Patients' satisfaction with Midazolam was 99% compared to 10% with lidocaine use (Figure 1). Patients' cooperation was 96% vs 60% between the Midazolam group and the topical anesthesia group respectively. In case of Midazolam, 4% of patients were restless, and an assistant was needed to complete the procedure. Paradoxical reactions (hyperactive or aggressive behavior) were recorded in 4% and 35% of Midazolam and Lidocaine groups respectively (Table 2). While 1% of patients could remember the withdrawal with Midazolam use and a few patients could remember the insertion of the endoscope, none felt pain during the procedure. On the other hand, patients with topical anesthesia remembered the insertion and the withdrawal, felt pain during the procedure, and faced difficulty in swallowing one day after the procedure (Figure 1). In terms of safety profile, only 1% of patients in the Midazolam group and 0% in the Lidocaine group were hypoxic (SpO₂ <95%) (Table 2). But none required oxygen. Only drowsiness, with a recovery time of 20 (±5) minutes, was seen in some patients of the Midazolam group. None of the patients developed arrhythmia in both groups.

Table I

Age of the patients	Midazolam group	Control Group (Topical anesthesia with Lidocaine gel 2% and Lidocaine spray 10%)
20-29	181	166
30-39	568	602
40-49	841	991
50-59	623	538
>60	23	24
Total	2236	2321

Table II*Sedation-associated safety profile during endoscopy*

Events	Midazolam group	Lidocaine group
Hypoxemia (SpO ₂ < 95%)	22 (1%)	0
Paradoxical reaction (hyperactive or aggressive behavior)	89 (4%)	812 (35%)

**Figure 1:** *Different patient parameters in endoscopic procedures***Discussion:**

In this cross sectional study, 4557 patients aged between 18 to 80 years were included (Table 1). In our study, patients' satisfaction and willingness to undergo repeated procedure were significantly higher in the Midazolam group compared to that of the Lidocaine group (99 versus 10 percent respectively) (Figure 1). These findings are consistent with that of a study done previously⁸.

Other than hypoxemia (in 1% of patients) and drowsiness like minor side effects, no major respiratory depression or adverse cardiac events were seen in Midazolam group. Patients had a better satisfaction level with Midazolam than that with topical anesthesia alone. Moreover, with the use of low dose Midazolam, the cost of the procedure remains within the affordability of most of the patients.

Conclusion:

Midazolam can be used as a safe and cheaper pre-medicative agent in UGI endoscopies. It not only reduces

the costs of the patients but also makes endoscopy less frightening. Especially for resource-poor countries like Bangladesh, Midazolam can be used safely without anesthetists and prior pre-anesthetic checkups. By increasing awareness and encouraging the usage of Midazolam, we can make endoscopies less painful and more patient-friendly.

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