Efficacy and safety of midazolam and ketamine in paediatric upper endoscopy

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ABSTRACT

Background and study aim: Upper endoscopy can be successfully carried out in children under deep sedation and anaesthesia. However, the best method of upper endoscopy for children who require gastrointestinal intervention has yet to be defined. The aim of this study is to investigate the efficacy and safety of the sedation induced by intravenous midazolam and ketamine during upper endoscopy in children.

Patients and methods: This study included patients ages 3–18 years who had undergone upper endoscopy. All subjects received IV midazolam and ketamine. During the intervention, hypoxia, tachycardia, bradycardia, hypertension, and hypotension were recorded. After the intervention, euphoria, dysphoria, vertigo, visual problems (such as diplopia and nystagmus), and emergencies (such as arrhythmia, convulsion, and hallucination), among other findings, were recorded. Older children who were capable of expressing themselves were questioned to help determine these conditions.

Results: The mean age of the study group was 11.9 ± 3.42 years; 54% of the patients were females, and 46% were males. During the upper endoscopy, hypoxia occurred in 9% of patients, mild hypertension in 14%, hypotension in 5%, tachycardia in 23%, bradycardia in 8%, and flushing-urticaria in 2%. After the upper endoscopy, one of the most common complications was sore throat, which occurred in 24% of patients. Vomiting was observed in 14% of patients, dizziness in 24%, diplopia in 27%, euphoria in 3% (5 patients), dysphoria in 4%, and hallucination in 4%. Of the total patients, 4% required oxygen supply with a face mask.

Conclusion: The results of our study showed that the use of IV midazolam and ketamine during upper endoscopy in children was safe and effective.

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August 2015. Ethics committee approval was received for this study. Informed consent was obtained from the families of the patients before the intervention. Patients with cardiac, pulmonary, neurologic, or metabolic disorders, hepatic failure, and known hypersensitivity to midazolam and ketamine were excluded from the study. Only patients with a score of 1 or 2 according to the classification of The American Society of Anaesthesiologists were included [8].

All patients received 0.1 mg/kg (max. 4 mg) midazolam (Dormicum; Roche, Istanbul, Turkey) and 0.5 mg/kg (max. 2 mg/kg) ketamine (Ketalar; Pfizer, Sandwich, UK) as a slow IV infusion given by an endoscopy nurse. The upper endoscopy was carried out by a paediatric endoscopist with the use of an EG530 WR gastroscope (9.4 mm in diameter; Fujinon, Tokyo, Japan). The efficacy of sedation was evaluated by the endoscopist according to the Ramsay Sedation Scale (RSS) [9], which gives patients scores ranging from 1 to 6 depending on their responsiveness and cooperation. According to the RSS scoring, R5 (deep sedation; the patient responds only to painful stimulation) was considered as a contraindication to an additional dose of midazolam. The patients were monitored over the whole duration of the intervention; the cardiac apex beat, peripheral oxygen saturation, and arterial hypertension were recorded by the nurse. All patients received 2 L/min oxygen with the use of a nasal cannula.

The side effects recorded during the intervention included hypoxia (peripheral oxygen saturation <90%), tachycardia (apex beat 30% higher than the age-adjusted normal rate), hypotension (apex beat 30% lower than the age-adjusted normal rate), hypoxia (peripheral oxygen saturation <90%), tachycardia (23%), bradycardia (8%), and flushing-urticaria (2%) (Table 2). After the upper endoscopy, 14% of the patients had vomiting. Dizziness occurred in 24% of patients, diplopia in 3%, euphoria in 4%, hallucination in 4%, and oxygen requirement supplied with a face mask in 4% (Table 3).

### Results

This study included 275 patients who had undergone upper gastrointestinal endoscopy in our endoscopy unit between August 2014 and August 2015. Of this total, 97 patients were excluded: 22 refused to participate; 6 did not complete the upper endoscopy; 63 had cardiac, pulmonary, neurologic, or metabolic disorders or hepatic failure; and 6 had known hypersensitivity to ketamine and midazolam. The remaining 178 patients completed the study. Our endoscopy success rate in patients sedated with the combination of midazolam and ketamine was 96.7%. The mean age of the study group was $11.9 \pm 3.42$ years; 54% of the patients were females, and 46% were males. Regarding the upper GIS endoscopy indications, dyspepsia occurred in 59%, coeliac disease in 12%, chronic diarrhoea in 3%, and other disorders (such as varices, foreign body ingestion, and corrosive oesophagitis) in 26%. Table 1 shows the distribution of patients according to age, gender, and indication. Fig. 1 presents the patient flow chart. Most of the patients were under R4 and R5 according to the RSS classification, as shown in the RSS distribution in Fig. 2. Most of the patients received midazolam at a dose of 0.1 mg/kg and ketamine at a dose of 0.75 mg/kg.

During the intervention, other complications emerged, including hypoxia (9%), mild hypertension (14%), hypotension (5%), tachycardia (23%), bradycardia (8%), and flushing-urticaria (2%) (Table 2). After the upper endoscopy, 14% of the patients had vomiting. Dizziness occurred in 24% of patients, diplopia in 3%, euphoria in 4%, hallucination in 4%, and oxygen requirement supplied with a face mask in 4% (Table 3).

### Table 1

<table>
<thead>
<tr>
<th>Patients N (%)</th>
</tr>
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<tbody>
<tr>
<td>Age (Mean ± SD)</td>
</tr>
<tr>
<td>Sex</td>
</tr>
<tr>
<td>Endoscopy indication</td>
</tr>
<tr>
<td>Suspected coeliac disease</td>
</tr>
<tr>
<td>Chronic diarrhoea</td>
</tr>
<tr>
<td>Others</td>
</tr>
</tbody>
</table>

### Table 2

<table>
<thead>
<tr>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dyspepsia 59</td>
</tr>
<tr>
<td>Suspected coeliac disease 12</td>
</tr>
<tr>
<td>Chronic diarrhoea 3</td>
</tr>
<tr>
<td>Other disorders 26</td>
</tr>
</tbody>
</table>

### Fig. 1

Patient flow diagram.

### Fig. 2

Comparison of patients according to the Ramsay Sedation Scale.

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Please cite this article in press as: Basturk A et al. Efficacy and safety of midazolam and ketamine in paediatric upper endoscopy. Arab J Gastroenterol (2017), http://dx.doi.org/10.1016/j.ajg.2017.05.004
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