COMPLICATIONS OF INTRAVENOUS DEEP SEDATION IN PEDIATRIC ENDOSCOPY

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ABSTRACT

Objective: It is accepted that sedation during endoscopic procedures is mandatory in children, however the mode of sedation and choice of medication varies among gastroenterologists. The use of intravenous sedation in pediatric endoscopy offers a safe and effective way of either conscious or deep sedation.

Methods: In order to investigate the safety and efficacy of intravenous sedation with meperidine and midazolam in pediatric patients, 120 patients who underwent endoscopy were evaluated. Vital signs and any reaction to sedative agents were noted during and after the endoscopic procedure.

Results: The complication rate of sedation with this combination was 19.1%, and all were transient with no residual sequelae. The most common complication was allergic skin reactions (15.7%). Transient hypoxia was seen in 1.7% of patients. The recovery time was 74.8 \pm 15.8 min. The endoscopic procedure was not postponed in any of the patients due to the complication of sedation.

Conclusion: It was concluded that intravenous deep sedation with meperidine and midazolam when administered by an experienced pediatric gastroenterologist and monitored closely is safe and effective with a low risk of complication.

Key Words: Sedation, Pediatric endoscopy

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The advent of fiberoptic endoscopy allowed direct visualisation of the mucosa of both the upper and lower gastrointestinal tract. Nowadays, the availability of newer and smaller endoscopes enable the diagnosis and treatment of various gastrointestinal

diseases in children (1-4). While almost all upper and lower gastrointestinal endoscopic procedures are performed under conscious sedation in adults, this is not always possible in children (5,6). Since children may be at a different state of cognitive development, it is not always possible to expect any cooperation during endoscopic procedures (7). The goals of sedation are to ensure the patient's safety, provide analgesia and amnesia, control behaviour during the procedure, enable successful completion of the procedure, and quickly return the patient to pretreatment level of consciousness (8). These goals can be achieved by either general anesthesia (GA) or deep intravenous sedation. The mode of sedation and choice of medication varies among pediatric gastroenterologists depending on the objective patient conditions (i.e. respiratory or severe cardiac compromise or severe mental or motor retardation), the lack of familiarity with intravenous sedation or concern for the patient's safety during intravenous sedation (9-11). Currently, most gastroenterologists use an opioid and benzodiazepine combination in children as well as in adults. The agents most commonly used for sedation and analgesia are midazolam and meperidine (12-14).

Diagnostic endoscopy with biopsy is generally considered to be safe. The majority of complications during endoscopy are caused by the sedation rather than the procedure itself.

The purpose of this study was to investigate the efficacy and safety of the deep intravenous sedation accomplished by meperidine and midazolam, and also to reveal the complication rate of the intravenous deep sedation during various endoscopic procedures in pediatric patients.

MATERIALS AND METHODS

All pediatric patients undergoing outpatient diagnostic upper and lower gastrointestinal procedures between

March 1995 and March 1996 were included to the study. Esophagogastroduodenoscopy (EGD) was performed by using the Olympus XP-20 (Optical Instruments Co., Tokyo, Japan) with an external diameter of 7.9 mm. The Olympus PCF-20 colonoscope (Optical Instruments Co., Tokyo, Japan) with an outer diameter of 11.3 mm was used for lower gastrointestinal examinations. A detailed explanation about the procedure and the sedation process was given to the family and the patient to reduce anxiety. An informed consent was obtained before the procedure. The parents accompanied the child to the endoscopy unit and stayed there until the child was full sedated.

After a safe venous access was established, the initial dose of 0.5 mg/kg meperidine was given slowly, and 1-2 minutes later the initial dose of 0.05 mg/kg midazolam was given. After the initial doses, meperidine was given at a dose of 1 mg/kg/dose which was titrated to a maximum of 4 mg/kg, and midazolam was given at a dose of 0.1 mg/kg/dose which was titrated to a maximum of 0.4 mg/kg. The medications were given at tandem with a few minutes between doses. Naloxone and flumazenil were always available within the endoscopy unit to reverse the action of meperidine and midazolam respectively whenever there was a life-threatening complication regarding sedation.

Heart rate, respiratory rate, blood pressure and oxygen saturation were monitored during the procedure and recorded every 5 minutes (PRO PAQ 102 EL Protocol System Inc., Baeverton, Oregon 97004 USA). Blow-by oxygen (5 L/min) was administered to the patients via an oxygen mask when the oxygen saturation decreased below 90% for longer than 15 seconds. Two endoscopy nurses were in attendance, and one was assigned to observe the patient and secure the endoscope, while the second was assigned to assist with the tissue biopsy handling. The patients were closely observed for stridor, hypoxia, hypotension, bradycardia, agitation, and inspected for any kind of allergic skin reactions such as local erythema, fascial flushing, urticaria, or maculopapular rash.

Recovery time was defined as the time elapsed between the end of the procedure and discharge from the endoscopy unit. The following criteria had to be met for discharge: the patient's vital signs had to be stable, and the patient should be awake and alert and able to follow simple commands.

Statistical analysis was performed using Student's t test for the comparison of two groups. A value of p<0.05 was taken as level of significance.

RESULTS

One hundred and twenty patients (64 boys, 56 girls, aging $2^{1}/_{2}$ months to 17 years) were enrolled in the study. The mean age of the patients was 7.4 ± 4.4 years. Sixty-eight EGD and fifty-two colonoscopies were performed. The mean dose of midazolam was similar in the upper and lower gastrointestinal endoscopy groups (0.33 ± 0.04 mg/kg versus 0.34 ± 0.05, respectively). The mean dose of meperidine was higher in the lower gastrointestinal endoscopy group (3.04 ± 0.35 mg/kg versus 3.42 ± 0.43). The mean recovery time was 74.8 ± 15.8 minutes in the study group.

Mean arterial blood pressure (MAP) was 89.4 ± 18.9 mmHg and mean heart rate was 101.6 ± 18.3 in the study. There were no statistically significant differences between baseline and 5, 10, 15, 20 minute MAP and heart rate measurements. Oxygen saturation was decreased by 2-6 % in patients younger than 5 years of age, and nasal oxygen was supplemented in all patients younger than 3-4 years of age. The complication rate secondary to sedation was 19.1% (23/120) in the study group, and all of them were mild and transient (Table I). The most common complication was allergic skin reaction observed in 15.8% (19/120) of the patients (Table I). One patient suffered from stridor, two from transient hypoxia, and one from agitation. The patient with stridor responded to 1 mg/kg intravenous corticosteroid, and the patient with transient hypoxia responded to supplemental oxygen. There was no difference in the sedation complication rate in EGD or colonoscopy groups (p>0.05). No serious cardiac or respiratory complications were observed. The endoscopic procedure was not postponed in any of the patients due to the complication of sedation. The procedures were successfully completed in all patients.

Table I. Complications observed during sedation in the study group.

n-23	%
1	0.8
1	0.8
2	1.7
8	6.7
7	5.8
3	2.5
1	0.8
	n-23 1 1 2 8 7 3 1

DISCUSSION

Intravenous sedation for adult EGD has been shown to be both effective and safe. Although endoscopic procedure is performed under conscious sedation in all adult patients, GA or deep intravenous sedation are methods of choice in children. The mode of sedation and choice of medication varies among pediatric gastroenterologists (9, 11).

Deep sedation can be defined as "a medically controlled state of depressed consciousness or unconsciousness from which the patient is not easily aroused" (8). In some centers GA is used in small children while in others it is used in all age groups. This variability depends on the training program of the gastroenterologist and/or his experience: The decision to utilise GA for an endoscopic procedure should be based on an objective patient condition such as age, accompanying problems (e.g. severe mental retardation or other neurological impairments), respiratory or cardiac compromise and the purpose of the endoscopy (e.g. removal of a foreign object). In our center we prefer intravenous deep sedation rather than the GA. When GA is selected the anesthesiologist is responsible for monitorization and sedation, and the endoscopist is no longer responsible for complications (15). But, GA has its own set of problems such as cost, requirements of special equipment and qualified staff, and problems directly related to the GA (e.g. loss of airway or hypersensitivity to general anesthetics or side effects of inhalational anesthetics) (9, 10, 16).

Currently, most gastroenterologists use an opiod (meperidine or fentanyl) and benzodiazepine (diazepam or midazolam) combination in children as well as in adults. Midazolam has replaced diazepam for endoscopic procedures because of its rapid onset of action, shorter duration of action, and reversibility of its action (17, 18). In our center all medications are administered with flowing intravenous fluid, and the doses of narcotics and midazolam are titrated in order to achieve a satisfactory and safe sedation. It is important to recognise that sedating agents should be titrated to meet the needs of the patient and the procedures to be performed, not to meet criteria of being in deep or conscious sedation. Some older children and adolescents may meet the criteria of conscious sedation, but it is not always possible for infants and small children. The mean total doses of both meperidine and midazolam are usually lower in adults than in children. This difference in doses was explained by the rapid metabolism and excretion of both midazolam and meperidine in children (18, 19).

Diagnostic endoscopy with biopsy is generally considered to be safe. The majority of complications during endoscopy are caused by the sedation rather

than the procedure itself. Transient side effects of sedation were detected in 19.1% of the study group. Allergic skin reactions such as local erythema, maculopapular rash, urticaria were the most common complications (15.7%). Transient hypoxia and stridor which were transient without any residual sequelae were noted in only 3.2% of these patients. In this study, oxygen was routinely administered to the patients who were younger than 3-4 years of age. Although available, none of the patients needed naloxone or flumazenil for the reversal of the action of meperidine or midazolam, respectively. Endoscopic procedure was not postponed in any of the patients due to the complication of sedation. The American Society for Gastrointestinal Endoscopy reported 1.35% complication rate of endoscopy in a collaborative study of 21000 adults (6). Serious cardiac or respiratory complications for an overall rate of 5.4/1000 procedures were reported. This study did not report mild side effects such as rash or transient hypoxia.

In a large prospective study done by Ament et. al., the overall complication rate was 1.7%, most of which was related to sedation (20). In a study done by Chuang et. al., potentially serious side effects were observed in 3.1% of children (13). Mild and transient side effects of sedation (e.g. fascial flushing, urticaria, phlebitis) and transient hypoxia were reported to be 19.1% and 9.6%, respectively in the same study.

The use of intraveous sedation in pediatric endoscopy offers a safe, effective, and less costly alternative to GA when performed by an experienced endoscopist in a well equipped endoscopy unit. To achieve acceptable results in intravenous sedation, we believe that the pediatric endoscopist should be trained in the administration of intravenous sedation. Also required are continuous monitorization of vital signs and oxygen saturation, adequate endoscopy personnel, adequate equipment (oxygen supply, aspirator, pediatric laryngoscope, and Ambu bags), and adequate facilities where the patient can be observed after the procedure.

The intravenous deep sedation in children, when administered by an experienced pediatric gastroenterologist and monitored closely, is a safe and effective way of sedation with a very low risk of complication.

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