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Retrospective analysis of deep sedation in pediatric population for endoscopic procedures: adverse events and outcomes

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Abstract

Background: Upper gastrointestinal endoscopy (E) and colonoscopy (C) procedures are not well tolerated in pediatric population. General anesthesia or sedation applied during gastroendoscopic procedures. This study is done to review our sedation practice and to evaluate the clinical effectiveness and side effects of an anaesthesiologist administered deep sedation for gastroendoscopic procedures outside the operating room.
Methods: After Institutional Review Board Approval, the charts of all children who underwent endoscopic procedure at the outpatient endoscopy suite under sedation, (Jan 2011- December 2011) were reviewed retrospectively.
Results: Deep sedation was used in 301 procedures, which 255 were endoscopic and 23 were colonoscopic procedures. Twenty-three children had both procedures performed in one session. Demographic details: Age [year, mean]: 10,1±5,1, Gender (M/F): 152/149, Body weight [kg, (mean±SD)]: 35.7±18.7. Severe bradycardia with oxygen desaturation was recorded in two patients. All procedures were carried out successfully. Emergence delirium was seen in only one patient who was the substance user. No significant side effect derived from intervention was observed during the procedures, except one case (perforation of the colon).
Conclusion: Deep sedation applied by anesthesiologist found to be adequately safe and appropriate for children during gastroendoscopic procedures

Key words: Child, Complication, Sedation, Ambulatory Anesthesia

Introduction

In paediatric patients, sedation or sedo-analgesia procedures are required when there is anxiety, fear of medical procedures, behavioural impairment and pain. Upper gastrointestinal endoscopy (E) and colonoscopy (C) frequently performed to diagnose and treat a wide range of gastrointestinal problems. These procedures are not well tolerated in paediatric population. For those reason endoscopic procedures under sedation or general anaesthesia is preferred option.

The aims and objectives of providing care during sedation or general anaesthesia on children are amnesia, motionless, safety, early discharge, and cost effective care. But sedation or general anaesthesia are not complication free applications. Furthermore endoscopic procedures are frequently performed outside the operating room (1-5). Significant complications during such procedures have been reported (6).

There exists a great variation in anaesthesia practice for paediatric endoscopy. Increased awareness of the complications associated with sedation during GI endoscopic procedures in children, the institution of modern monitoring modalities to identify these complications, and the involvement of the anaesthesiologists in looking after these children in, or outside, the operating room is optimal for the safety of these patients (1-8).

We aim to present adverse events and outcomes at endoscopic procedures under deep sedation applied by the anaesthesiologist in paediatric population

Material and method

This study was approved by the institutional review board at Gazi University Faculty of Medicine. The anesthesia database at our hospital during January 2011-December 2011 interval was searched for all patients less than 19 years of age referred for gastro endoscopic procedures under deep sedation. All interventions were performed by same team of the pediatric gastroenterologist. All sedation was given by a staff anesthesiologist. Following demographic and clinical data were obtained:

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age, gender, weight, ASA classification, time of endoscopy procedure, oxygen delivery method, doses of the anesthetics, and hemodynamic variables during sedation, complications, and any therapeutic interventions performed.

Procedural and resuscitative equipment of a size and type appropriate for pediatric use was been readily available during procedures. There were no premedication's prior to the procedure.

For all patients EKG, non-invasive blood pressure and SpO2 monitoring were used. All patients received supplemental O2 at 2-3 l/min through nasal canula. Sedation level was sustained with sedation agent as University of Michigan Sedation Scale (UMSS) (9) scores (3,4).

Post-Anesthetic Discharge Scoring System (PADSS) was used to discharge of the patients from endoscopy suit, and total score≥9 was considered for discharge (10). The effectiveness of intravenous sedation was defined as successful completion of the procedure. Sedation-related complications were defined as desaturation (oxygen saturation<94%), bradycardia (heart rate<20% than initial values), need for supplemental oxygen (above baseline supplementation). Intervention related complications were recorded too.

Statistical analysis

The statistical analyses were performed with SPSS 17.0 software program and $p<0.05$ was considered statistically significant. Data were presented as mean value±standard deviation (SD), (Min-Max), n, (%).

Kolmogorov-Smirnov test was performed for the measurable parameters in order to determine whether the range is normal. Parametric values were evaluated with one-way ANOVA with Bonferroni adjustment. Numerically equality be achieved and non-parametric values were studied with Kruskal-Wallis test and the differences were evaluated with Mann-Whitney U test. HR and SpO2 parameters were analysed using repeated-measures analysis of variance (ANOVA), with Bonferroni's adjustment. Complication and/or side effects were compared using Chi-square and Fisher's exact tests

Results

Three hundred and one procedures (n=255 E, n=23 C, n=23 E+C) were performed on 301 children (Table 1). Supplemental oxygen was given via nasal cannula, ambu or endotracheal intubation (Table 2). Doses of used anesthetics, anesthetic agents or combinations in terms of groups, quantity of the used anesthetic agents and procedure time were shown in Table 3, Table 4 and Table 5 (respectively). Time dependent heart rate and SpO_2 variables were shown in Figure 1 and 2. Complication and/or side effects in terms of E, C, and E+C groups were shown in Table 6. Significant desaturation was recorded in seven patients (lowest SpO_2 values were 55%). Endoscopic intervention was stopped and the children were ventilated 100% O_2 by ambu mask (n=5) or endotracheal tube (n=2) than SpO_2 values were normalized. The procedures were then completed uneventfully. No significant side effect derived from intervention was observed during the procedures except one patient (perforation of the colon) and then endotracheal intubation was attempted. Colonic perforation case was carried out to the operation room for urgent surgical operation. Except this case all procedures were carried out successfully. Severe agitation and delirium was seen during recovery period in one patient who was the substance addicted

Discussion

This retrospective study demonstrates clinical effectiveness and side effects of deep sedation applied by the anesthesiologist for pediatric gastro endoscopic procedures.

The aims and objectives of providing sedation on children for endoscopic procedures are: allowing the children to tolerate the unpleasant procedures, remaining motionless, amnesia, preventing complications, ensuring safety, ensuring early discharge from the facility to home providing high quality and cost effective care. This also requires careful consideration of the patient, the endoscopy facility, and the variables of the procedure itself. Patient factors include age, weight, concurrent diseases, airway assessment, pre-procedure anxiety, and pain tolerance. Procedure variables include the amount of anticipated discomfort, the duration of examination, and how invasive the procedure will be. Although GI endoscopy is generally considered safe, the procedure does have a potential for complications.

For pediatric gastroendoscopic procedures general anesthesia or sedation are applied in anesthesia practice. It is important to recognize that most pediatric sedation are deep and risk and adverse events occur more than adults (1-5).

In our work; parents of the patients were informed of and agree to the administration of anesthesia, including discussion of its benefits, risks, and limitations and possible alternatives. Patient's historic details just like; diseases of major organ systems, snoring, stridor, sleep apnea, allergies, prior adverse reaction to drugs, current medications, time of and type of last oral intake, alcohol, or substance use are obtained by direct questions. Furthermore physical examination (measurement of vital signs, determination of baseline level of consciousness, and assessment of the cardiopulmonary system was performed.

Table 1. Demographic properties and operation data [Mean±SD (Min-Max), n]

Number of the patient (n)	301
Gender (Male/Female)	152/149
Age (Year)	10,16±5,19 (0,25-18)
Weight (kg)	35,74±18,72 (5-83)
ASA (I/II)	265/36
Time of endoscopy procedure (minute)	20,36±12,75 (5-75)

Table 2. Oxygene delivery method [n (%)]

Devices	n, (%)
Nasal canula	294 (98)
Ambu	5 (1,4)
Endotracheal entubation	2 (0,6)

Table 3. Doses of anesthetics [n, Mean±SD (Min-Max]

IV Pharmacologic agents	n	Mean±SD (Min-Max)
Propofol (mg)	261	112,17±60,31 (10-310)
Midazolam (mg)	284	0,91±0,24 (0,5-2)
Ketamine (mg)	144	19,58±13,19 (5-70)
Fentanyl (µg)	2	37,50±17,68 (25-50)

Table 4. Used anesthetic agents or combinations [n, (%)]

Used anesthetic agents	E (n=255)	C (n=23)	E+C (n=23)
Propofol	15	-	-
Midazolam+Propofol	126	11	4
Midazolam+Ketamin	35	1	3
Midazolam+Ketamin+Propofol	77	11	16
Sevoflurane	2	-	-

Table 5. Quantity of the used anesthetic agents and procedure time [Mean±SD (Min-Max)]

	E (n=255)	C (n=23)	E+C (n=23)	p**
Propofol (mg)	104,29±53,26 (10-270)	167,73±80,23* (40-300)	137,25±71,85* (20-310)	<0,0001
Midazolam (mg)	0,91±0,25 (1-2)	0,91±0,20 (0,5-1)	0,94±0,23 (0,5-1,5)	0,844
Ketamin(mg)	18,28±12,29 (5-70)	15,58±10,32 (5-45)	30,00±15,55&*, (5-60)	0,002
Fentanil (µg)	-	50	25	-
Procedure time (min)	10,06±6,13 (5-45)	37,17±13,38* (10-75)	50,87±10,52*,& (30-75)	<0,0001

p** p<0.05 Kruskal-Wallis Test
*p<0.05 Comparison with Group E
&p<0.05 Comparison with Group C

Table 6. Complication and/or side effects in terms of E, C and EC groups [n (%)]

	E (n=255)	C (n=23)	E+C (n=23)	p
Nausea/vomiting	2 (0,8)	-	-	X^2=0,663, p=0,718
Desaturation (94≤)	5 (2)	1(4,5)	1 (4,5)	X^2=0,829, p=0,661
Bradycardia	1 (0,4)	-	-	-
Respiratory distress	2 (0,8)	1(4,5)	-	X^2=2,024, p=0,364
Allergy	2 (0,8)	1(4,5)	-	-
Colon perforation	-	1(4,5)	-	X^2=2,024, p=0,364

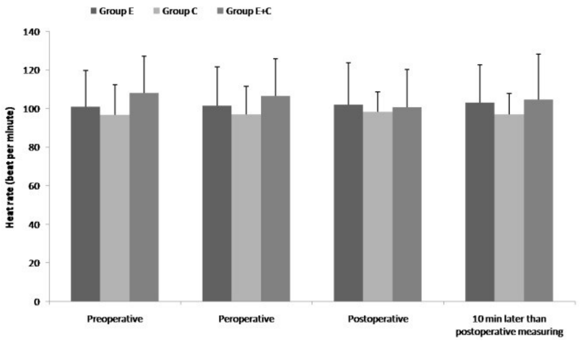

Figure 1. Time dependent heart beat rate in terms of groups

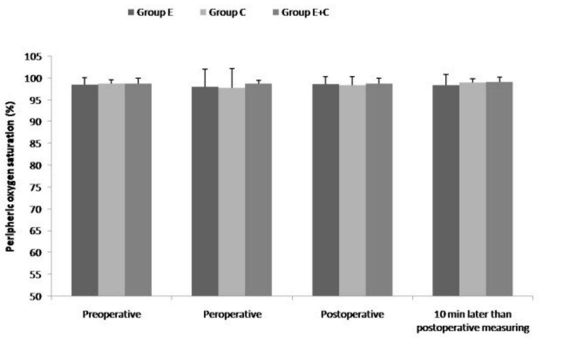

Figure 2. Time dependent SpO2 values in terms of groups

Thakkar et al (4) found that, the younger the age group, the higher the ASA class and intravenous (IV) sedation as risk factors for developing complications. Selection of patients according to this risk stratification may help to prevent or reduce complications associated with the procedure (5). In our series all the patients were in ASA I-II class.

There are no absolute guidelines as to timing of fasting before administration of sedation because of the absence of supporting data with regard to a direct relationship between duration of fasting and risk of pulmonary aspiration. The ASA guidelines recommend that patients should not consume fluids or solid foods for a sufficient period of time so as to permit adequate gastric empting (11, 12). In our clinic; patients were prevented from taking clear fluid, breast milk, light meal or heavy meal orally for 2, 4, 6 to 8 hours (respectively). No patient had pulmonary aspiration related complication in our series.

Monitoring is essential during sedation and recovery period. Pulse oximetry is a valuable tool to pick up oxygen desaturation but may not adequately reflect hypoventilation, apnea, impending hemodynamic instability, or vasoconstrictive shock. In particular, patients may be well saturated with oxygen and still experience significant CO2 retention. Capnography has emerged as a noninvasive way of measuring patient ventilation that may be especially useful in patients undergoing deeper levels of sedation (11-14). Malviya et al (7) picked up desaturation in 5.5% of patients and achieved a reduction in bad outcomes. Hypoxemia secondary to depressed respiratory activity is the most important risk factor for near misses and death during sedation for children undergoing procedures. Early detection may be valuable in avoiding morbidity and mortality in pediatric sedation procedures. In our series patients were observed closely. Desaturation was observed in 7 patients. Although SpO2 was monitored EtCO2 was not monitored causes of technical failure.

Oxygen was administered by nasal cannula in all of our patients. This practice is a matter of debate because it could affect the timely detection of hypoventilation (13,14). On the other hand, the ASA guidelines recommend supplemental oxygen during sedation, and many authors follow this recommendation (11,12).

In our clinic oropharyngeal topical anesthesia just before endoscopy was not used because topical anesthetic agents have been associated with serious adverse effects (aspiration, anaphylactoid reactions) (15).

There aren't exact consensuses about anesthetic management of children for endoscopic procedures, and general anesthesia, sedation, or non-sedation (awake) methods are using1-3. In recent years, 4 levels of sedation were identified, which stretch along a continuum without clear boundaries: minimal sedation or anxiolysis, moderate sedation, deep sedation, and general anesthesia. To date, these levels of sedation have been defined by a patient's response to verbal, light tactile, or painful stimuli, although they are generally also associated with physiologic changes in patient vital signs. Deep sedation is a drug-induced depression of consciousness, during which patients cannot be easily aroused but respond purposefully to repeated or painful stimulation. The ability to maintain ventilator function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained (16). In our series deep sedation level [UMSS scores 3-4 (9)] was intended.

Gastroscopy is a widely-used method for detecting upper gastrointestinal diseases. However, hypoxias, elevations of blood pressure and heart rate have repeatedly been demonstrated during gastroscopy (1-5). These potentially harmful side-effects are sometimes life-threatening, particularly for patients with accompanying disease. Although it has been shown that sedation during gastroscopy helps to prevent the increase in blood pressure and heart rate, hypoxia still remains a potential risk following administration of sedation Administration of sedation incurs additional medical expenditure and risks. The most common serious and life-threatening complications related to sedation are respirator in ethology. Of these, the most serious is aspiration because its consequences may be impossible to correct or prevent once substantial aspiration has occurred. Even minor episodes of aspiration may result in prolonged coughing, bronchospasm, or pulmonary infections. Thus, avoidance of pulmonary aspiration is critical for safe endoscopic practice. These events are related to the depth of sedation and may result from suppression of respiratory drive in the central nervous system or from airway collapse that occurs with sedation. Cardiovascular complications are less commonly life threatening during endoscopy, and, when life threatening, they most often follow a period of inadequate ventilation and hypoxemia. Nevertheless, the physiologic response to sedation and the physical stress of endoscopy is quite variable. Individual patients have a susceptibility to vagally mediated bradycardia and hypotension that can be precipitated by stretching the sigmoid mesentery during passage of a colonoscope. In other patients, marked tachycardia may develop if the procedure is started when they are inadequately sedated, particularly during upper endoscopic procedures. Hypertension is seen commonly during endoscopic procedures. Although hypotension and hypertension during endoscopy very rarely result in permanent complications, they occasionally reach levels for which corrective action is appropriate. Atrial or ventricular arrhythmias are rarely precipitated by sedation or stress of the procedure (4,5,7,12,17,18). In works of Deenadayalu et al (19) a worldwide multicenter safety review of more than 521,000 patients was conducted. Mask ventilation rates were 0.4:1000 patients for upper endoscopy and 0.1:1000 patients for colonoscopy. Endotracheal intubations, neurologic injuries, and death occurred in 4, 1, and 3 patients, respectively. The 3 deaths occurred in patients with significant comorbid illnesses such as widely metastatic malignancy and polysubstance abuse.

Although gastrointestinal endoscopy occasionally is a safe procedure, significant complication can occur as a result of instrumentation, such as bleeding, perforation and infection. In our series rather than seventeen cases (patients with nausea/vomiting, desaturation, severe bardycardia, respiratory distress, colon perforation, allergy) vital parameters were stable all procedures long. All procedures except one (colonic perforation) carried out successfully.

Sedation is applied by nonanesthesiologist too. Motas et al (20) in a prospective study of pediatric population undergoing sedation by non-anesthesiologists for various procedures reported failure to achieve sedation in 12%-28% using BIS or the UMSS respectively as a monitor of sedation. Malviya et al (7), in another prospective study involving 1140 children sedated by a non-anesthesiologist for various procedures, reported a 20.1% incidence of adverse events. These included inadequate sedation, low oxygen saturation, airway obstruction, apnea needing bag mask ventilation, and excitement and agitation. Lightdale et al (21) prospectively reviewed more than 2300 endoscopic procedures and reported agitation, respiratory events, incomplete procedures, hemorrhage and perforation as adverse events. Agitation was significantly associated with endoscopist-administered sedation. Mamula et al (22) in a retrospective review of conscious sedation in children also reported approximately 20% incidence of non-life threatening adverse events. Levis et al (23) reported a 20% incidence of recall in children following esophago-gastroduodenoscopy, thus increasing their level of anxiety and reluctance to accept subsequent procedures. Thakkar et al (4), in a cross sectional retrospective study of 10.236 upper GI endoscopic procedures in 0-18 year old children reported an overall immediate complication rate of 2.3%. IV sedation with midazolam, fentanyl, meperidine or ketamine was used in 46% of procedures, whereas 54% procedures were performed under GA. Cardiopulmonary complications were reported in 79.9% of procedures, gastrointestinal complications were reported in 18% of procedures, whereas in 5.9% of procedures complications such as prolonged sedation, drug reaction or rash were reported. All complications were non-fatal and most were hypoxia- related and reversible. They identified a younger age, higher ASA class, female sex and IV sedation as risk factors for developing complications. A complication rate of 1.2% was associated with procedures performed under GA as compared to a 3.7% incidence associated with IV sedation. After adjusting with all other variables, they reported IV sedation to be independently associated with a cardiopulmonary complication rate 5.3% times higher when compared to GA. Agostomi et al (24) reported on complication during sedation for gastroendoscopic procedures in 457 pediatric cases. In their series, complication rate 22% (bradycardia), and 4.4% (hypotension). In a study by Barbi and colleagues (25), major desaturation was noted in 0.7% of all the children, and transient desaturation that resolved spontaneously occurred in 12% of all the procedures. Additionally, the study by Yıldızdas¸ et al (26) demonstrated that the use of propofol and midazolam/fentanyl in 126 children had 16.6% incidence of respiratory depression as shown by high end-tidal carbon dioxide (>50 mmHg). The high incidence of respiratory depression reflected the better detection of respiratory depression by the use of end-tidal carbon dioxide. In our series 17 complications or side effects were seen totally.

Conclusion

In conclusion our data suggest that deep sedation (with propofol, midazolam, ketamine, fentanyl, or their combination) which managed from anesthesiologist presents advantages in terms of safety, and depth of sedation. Although our sedation experiences were not complication free, all sedation related complications were transient and easily treated with no permanent sequelae. We recommend deep sedation for pediatric gastroendoscopic procedures applied by anesthesiologists

Conflict of Interest

The authors declare no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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