A PEDIATRIC SEDATION/ANESTHESIA PROGRAM WITH DEDICATED CARE BY ANESTHESIOLOGISTS AND NURSES FOR PROCEDURES OUTSIDE THE OPERATING ROOM

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Objective To examine the performance of a pediatric sedation team working according to a specific protocol and to assess parental satisfaction with the service.

Study design A descriptive observational study of all procedures performed by the sedation team (comprising sedation-trained pediatric intensive care nurses and dedicated anesthesiologists) in a university hospital over 6 years. Data collected included demographics, procedure and location, sedation staff present, sedation failure, drugs used, requirements for escalation of sedation, complications, and parental satisfaction.

Results Sedation was provided for 8760 procedures in 5554 children. The sedation nurse started 1769 (20%) procedures using triclofos sodium and required the assistance of the anesthesiologist in 115 (6.5%) cases. The remaining 6991 (80%) cases were performed by the anesthesiologist, predominantly using propofol (in 72.5% of cases). No cases were deferred as a result of insufficient sedation. Adverse events were recorded in 153 (1.7%) children. Of these, 132 (86%) were mild decreases in oxygen saturation. Three children were not discharged as a result of oversedation. Feedback indicated that 95% of parents were very satisfied with the sedation service.

Conclusion A dedicated sedation team using a written protocol provides a service with minimal case cancellation, zero sedation failure, very good safety, and excellent parental satisfaction. ***(J Pediatr 2004;145:47-52)***

See editorial, p 10.

Providing sedation/anesthesia techniques during the performance of diagnostic and therapeutic procedures on children decreases anxiety, discomfort, and pain and may improve child well being. In addition, sedation/anesthesia reduces the child's movement and thus may increase the success rate of the procedures required. As a result, over the last few years there has been increasing interest and considerable demand for sedation in the pediatric population.[1] Levels of sedation have been defined,[2] and criteria for monitoring and supervision by medical teams have been recommended for the different procedures, which require different levels or depths of sedation. Moderate and deep sedation, along with general anesthesia, have been considered acceptable to facilitate the performance of diagnostic or therapeutic procedures.

Such sedation/anesthesia services have been provided by nonanesthesiologist physicians, nurses, and anesthesiologists in many institutions. Both the American Society of Anesthesiologists (ASA) and the American Academy of Pediatrics (AAP) have published recommendations regarding performance of sedation by nonanesthesiologists.[2,3] For moderate sedation, the AAP recommendations suggest that a single practitioner may both administer the sedation and perform the required procedure. It is recommended that the practitioner be competent in the use of sedation techniques and be able to manage complications. Basic Life Support certification is the minimum requirement and Pediatric Advanced Life Support certification is strongly recommended. Support personnel should be available to monitor the patient and assist in resuscitation (Basic Life Support certification strongly recommended). For deep sedation, AAP and ASA guidelines are

ASA	American Society of Anesthesiologists	AAP	American Academy of Pediatrics

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Table I. Preoperative fasting orders

Ingested material	Minimum fasting period (h)
Clear liquids	2
Breast milk	4
Infant formula	6
Nonhuman milk	6
Light meal	6
Contrast material	1

quite similar.[2,3] Both recommend the presence of an independent observer in addition to the practitioner performing the procedure to monitor the child's vital signs, the patency of the airway, and to be able to recognize and treat complications.

In our institution, a specific pediatric sedation protocol has been developed. The protocol is presented, and data regarding its usage over 6 years is detailed.

METHODS

Between May 1996 and May 2002, data were collected prospectively on all children younger than aged 18 years referred to the sedation service at the Hadassah University Hospital, a 700-bed urban tertiary referral center. Sedation/anesthesia was administered by the sedation service as required and for all procedures within the hospital but outside the operating rooms. All children referred to the sedation service were included in this survey. The sedation team comprised two nurses trained in pediatric intensive care and two dedicated pediatric anesthesiologists. These nurses were given a special sedation course, which included lectures, simulation of crisis scenarios, and airway management in the operating room. Personnel involved in the sedation unit were assigned solely to anesthesia/sedation performed outside the operating room. During night calls or weekends, the anesthesiologist on call took care of the very few children needing anesthesia/sedation outside the operating room. The different procedures were performed according to a weekly schedule.

The Institutional Ethics Committee approved the performance of this prospective observational study without the need for informed consent.

The protocol used by the sedation service was as follows:

For patients not admitted to the hospital, a few days before the required procedure a telephone evaluation was performed by the sedation team nurses with the child's parent or guardian. For hospitalized children, parents/guardians were interviewed, with additional information being provided by the treating physician or ward nurse. During this evaluation, demographic details including the child's age, weight, and ASA physical status were recorded as well as the type of procedure required, the indication, the hospital location, and the child's medical history. At the conclusion of the telephone interview, an information leaflet was sent to the family by mail and an explanation of the procedure and pre-procedure fasting requirements was provided (Table I).

The anesthesiologist was informed by the team nurse about all patients and was consulted for cases that were considered to be complicated, eg, ASA status III or IV, premature babies or postpremature children, and complicated procedures.

On the day of the procedure, a focused physical examination was performed by the anesthesiologist, including an evaluation of the airway for conditions that might render intubation or mask ventilation difficult. Children who were found to have an acute respiratory tract infection that had not been present at the time of the telephone interview, or that had not been detected at that time, had their procedures deferred for at least 2 weeks if not considered urgent. Informed consent was obtained from the parents or the legal guardians.

At this point, patients were divided into two groups, those who would be treated by the nurse alone and those who would require the presence of the anesthesiologist. The division was based on the type of procedure concerned and the complexity of the child's medical history. Nurses were allowed to sedate healthy children, older than aged 1 month, for noninvasive procedures where visual contact with the child was maintained at all times. In all other cases, sedation was performed only in the presence of an anesthesiologist.

In every location where sedation was performed, the environment was in compliance with AAP and ASA guidelines. At locations where the sedation nurse was to work alone, the only additional requirement was for the presence of a pulse oximeter. The anesthesiologist was provided with a mobile anesthesia trolley that included an anesthesia machine suitable for small children (Fabius anesthesia machine, North American Dräger, Telford, Penn), a scavenging system, an emergency oxygen tank, and routine anesthesia monitors (pulse oximetry, electrocardiogram, automatic blood pressure, capnograph, precordial stethoscope, and temperature probe). In certain locations, specialized equipment was provided, such as closed circuit television in the radiotherapy suite and nonferrous anesthesia and monitoring equipment in the magnetic resonance imaging suite.

The sedation nurse was limited in drug administration to an oral dose of triclofos sodium (triclofos sodium is the phosphate ester of trichloroethanol, the pharmacologically active metabolite of chloral hydrate. It results in less gastric irritation and has a less unpleasant taste than chloral hydrate, and it is, therefore, more acceptable for oral administration in children) 100 mg/kg (maximum dose: 2 g). The sedation nurse was not permitted to re-dose or to increase the dose. In the event that adequate sedation was not achieved or a complication arose, the anesthesiologist was called to see the patient and to deepen sedation or treat as required. The anesthesiologist was not limited in choice of drugs or anesthetic techniques for these cases or for other cases. The anesthesiologist was free to adapt the sedation technique, the drugs used, the routes of administration, and the level of sedation to the individual circumstances of the child and the procedure. Drugs were administered in the presence of the child's

Table II. Demographic data for the 5554 patients included in the survey

	n (%)
Total No. of Procedures	8760
Inpatients/Outpatients	2549 (29.1) /6211 (70.9)
Sex (M/F)	4870 (55.6) /3890 (44.4)
Age	
<1 y	902 (10.3)
1-2 y	1586 (18.1)
2-5 y	2943 (33.6)
5-10 y	2190 (25.0)
10-15 y	937 (10.7)
15-18 y	202 (2.3)
ASA physical status	
I	2339 (26.7)
II	5641 (64.4)
III	745 (8.5)
IV	35 (0.4)

parent(s) until the child was no longer awake. Oxygen was administered in all cases.

A sedation chart that became part of the patient's record was completed in all cases and included medications administered, depth of sedation achieved, duration of sedation, vital signs, monitoring used, and adverse events. Depth of sedation (moderate, deep, or general anesthesia) was assessed according to previously published scales and guidelines.[2] Recorded adverse events included oversedation, desaturation (90% or 10% below baseline for more than 30 seconds), airway obstruction that resulted in oxygen desaturation or required an airway intervention (such as jaw thrust, extension of the head, nasal airway insertion), cardiovascular events, adverse drug reactions, and requirement for escalation of care (such as admission to a ward for ambulatory patients or to an intensive care unit for hospitalized patients).

Children were discharged to the care of a responsible adult when they were alert and had returned to baseline activity. Instructions concerning food intake, medications, and observation for possible late complications were given to the parents or the guardians. Before discharge, a postsedation parental feedback form was completed. The parents were asked to express their degree of satisfaction with the sedation service (very satisfied, satisfied, not satisfied).

The data recorded in the sedation chart by a research nurse and parental feedback form composed the database for this survey.

RESULTS

During the 6-year study period, sedation/anesthesia was provided for 8760 procedures in 5554 children of varied ASA status from aged 1 day to aged 18 years (Table II); 927 children underwent more than one procedure. Fifteen children (0.3%) were refused sedation when assessed in the hospital: 12 had an acute upper respiratory tract infection, and 3 children had eaten a full meal before coming to the hospital. Children whose procedures were deferred based on the telephone interview are not included.

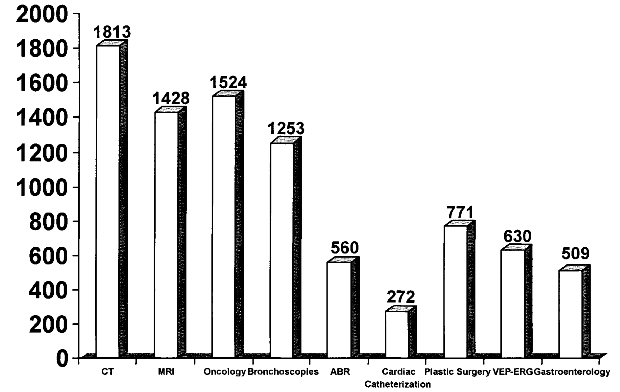

Figure. Numbers and distribution of procedures performed under sedation and/or anesthesia between May 1996 and May 2002.

Sedation/anesthesia was administered in a wide variety of locations within the hospital (Figure). The nurses spent an average of 30 minutes for each case (including the interview, the preparation of the location, and the recovery of the child), whereas the anesthesiologist spent an average of 60 minutes for each case.

A pool of 3003 procedures met the definition given earlier for procedures that the sedation nurse could perform alone (computed tomography, auditory brain stem response, visual evoked potentials-electroretinography). Patient characteristics determined that the anesthesiologist be present in 1234 procedures, meaning that the sedation nurse started sedation alone for 1769 procedures (58.9% of the 3003 potential cases). All children sedated by the nurse received only triclofos sodium 100 mg/kg. Sedation was insufficient in 115 cases (6.5% of 1769), necessitating the assistance of the anesthesiologist. Subsequently, all cases were concluded with the satisfactory performance of the procedure required. In 3 cases, the child was not sufficiently awake to be discharged home at the end of the day and had to be admitted overnight. All 3 children had received triclofos sodium only and were discharged the following day without further complication. For cases performed by the anesthesiologist, a wider range of drugs was employed including propofol for 72.5% of cases and other anesthetic drugs as shown in Table III. All these cases were also concluded with the satisfactory performance of the procedure required.

The majority of procedures were performed under deep sedation (7761, 88.6%), including all cases completed by the nurse alone. General anesthesia was required either as a first option when an airway intervention (such as a laryngeal mask airway or a tracheal tube insertion) was necessary or as a result of inadequate initial sedation for 938 (10.7%) procedures, whereas 61 (0.7%) procedures were performed with moderate sedation (Table IV). All the moderate sedation procedures

Table III. Sedative drugs used

	Anesthesiologist*	Nurse
Propofol	72.5%	
Triclofos sodium		14.3%
Midazolam	11.2%	
Ketamine	0.5%	
Halothane-sevoflurane	10.8%	
Fentanyl	36.4%	

*The total is more than 100% because drugs may have been used in combination.

Table IV. Depth of sedation

	Nurse	Anesthesiologist
Moderate	0	61 (0.7%)
Deep	1769 (20.2%)	5992 (68.4%)
General anesthesia	0	938 (10.7%)

were painless, required only midazolam, and were carried out for children older than aged 15 years.

Adverse events were reported in 153 (1.7% of all) cases, including the 3 children admitted to the hospital mentioned earlier (Table V). One additional child required hospitalization after bowel perforation during endoscopy. This complication was not related to sedation/anesthesia. No other children required hospital admission. No procedures were cancelled as a result of insufficient sedation or complications of sedation/anesthesia, and no children were returned to the hospital after discharge for sedation-related complications.

The most frequent adverse event recorded was a decrease in oxygen saturation, which occurred in 132 cases (1.5% of all cases), all under the care of an anesthesiologist. All these children were sedated either in the oncology clinic (35 patients) (where some refused to accept an oxygen mask before sedation) or for flexible bronchoscopy (97 children), where decreases in oxygen saturation are frequent. All these children had received propofol as the sole sedative agent. The oxygen saturation recovered spontaneously in 74 children and after an increase in oxygen flow in the remaining 58 children. Postsedation vomiting was noted in 6 children (0.07% of all cases) on arousal and resolved spontaneously with no respiratory or other complications and without the need for hospital admission. Finally, cardiac arrhythmia that did not require specific treatment was recorded in 12 children undergoing cardiac angiography.

The postsedation parental feedback form was completed by all parents and showed that 95% of the parents were very satisfied and 5% were satisfied with the sedation service.

DISCUSSION

We presented data derived from a large prospective survey examining pediatric sedation/anesthesia in a tertiary academic hospital. The data show that in the hands of a dedicated team, pediatric sedation/anesthesia is reliable, safe, and much appreciated by children's families.

Table V. Recorded anesthesia-related adverse events

Complication	n*	%
Desaturation	132	1.5
Higher flow of oxygen needed	58	0.7
Resolved spontaneously	74	0.8
Cardiac arrhythmias	12	0.1
Vomiting	6	0.07
Unscheduled hospitalization	3	0.03

*Out of 8760 procedures.

Medical procedures without sedation/anesthesia can be unpleasant for children, their parents, and healthcare providers. Young children (younger than aged 8 years) show higher levels of stress than older children,[4] and their parents may be less able to provide reassurance before a medical procedure. Children who undergo frequent invasive procedures will develop more medical fears, a lower sense of control over their health, and ongoing posttraumatic stress responses.[5]

Pediatric sedation/anesthesia is characterized by two main problems: medical complications related to the sedation and administrative issues resulting from procedure cancellation, usually as a result of insufficient sedation. The majority of complications arising from sedation/anesthesia relate to control of respiration/ventilation, with either airway obstruction (positional or related to secretions), hypoventilation, or apnea leading to hypoxemia. Children have a high metabolic rate and increased oxygen consumption when compared weight-by-weight with adults. In addition, they have a smaller functional residual capacity. Children therefore develop hypoxemia more rapidly than adults after cessation of ventilation for any reason. The ASA guidelines for sedation by nonanesthesiologists stress that a primary cause of morbidity associated with sedation/analgesia is drug-induced respiratory depression,[2] and a series examining 95 critical events after pediatric sedation cited hypoxia as a central mechanism to poor outcome in all cases.[6] The incidence of respiratory complications during pediatric sedation ranges from 0.8% to 9% for hypoxemia[7-12] and from 1.3% to 6% for airway compromise.[10,13-15] The 1.5% incidence of hypoxemia described in the present study is comparable to these figures, although most of the cases occurred in children undergoing bronchoscopy, a procedure in which hypoxemia is an inherent complication.[16] Pulse oximetry is not sufficient to detect the respiratory complications of sedation. We think that close clinical monitoring of the breathing pattern of the patient is the best way to detect such complications. End-tidal carbon dioxide may be used for early detection of airway obstruction and as an "apnea" monitor in a non-intubated child.

Undesirable outcome after pediatric sedation has been associated with the use of drug combinations[17] or drugs with long half lives such as pentobarbital and chloral hydrate,[18] the use of nitrous oxide,[17,18] drug overdose, inadequate patient assessment, inadequate monitoring, inadequate recovery procedures, sedation performed by untrained personnel, sedation performed out of the hospital, and premature discharge (FDA study: Report of Anesthesia and Life Support Advisory Committee, 3/94FDA, Rockville, Maryland). The protocol suggested earlier addresses almost all of these issues as it refers to all aspects of patient care from the pre-procedure assessment to patient discharge. In addition, the sedation service rests on the immediate availability of a dedicated qualified pediatric anesthesiologist. Anesthesiologists by training and with experience have a good working knowledge of clinical pharmacology, are used to working with sedative drugs, and are familiar with the expected side effects. Anesthesiologists also are experts in airway management and resuscitation and are used to closely monitoring and treating obtunded patients. Moreover, they are not involved in performing the procedure per se. These qualities ideally qualify the anesthesiologist to administer safe sedation/anesthesia and to prevent or treat complications.

Use of the suggested protocol leads to a zero procedure-cancellation rate once sedation/anesthesia had been started. Failed or inadequate sedation leads to cancellation of procedures, anguish for the child and family, financial loss, and possible delays in diagnosis and treatment. The reported incidence of inadequate or failed sedation ranges between 3% and 16%.[7,8,19,20] Factors that have been found to be associated with failed sedation include the use of a single agent[7]; sedation in babies less than aged 1 year[8]; older children, especially with mental retardation or autism[7]; and ASA status III or IV.[7] The level of skill and autonomy of the practitioner administering the sedation has not been assessed as a causative factor of failure, although in many protocols, if a nurse alone is administering sedation without further backup, both the doses of drugs and the use of drug combinations may be limited.[19,21] These limitations are justified as even triclofos sodium used alone can cause respiratory depression in sufficient dose and more so when combined with other drugs.[17,22,23] The protocol suggested in the present study addresses these issues as it provides both a rigid set of rules for the administration of sedation by a nurse and the flexibility of an anesthesiologist "on call" who is able to escalate sedation both in terms of drugs and doses until adequate conditions are achieved.

As described, sedation administration is divided between anesthesiologists and nurses. The care provided by the nurses allows the physicians to participate in an increased number of cases necessitating their presence. Criticism might be leveled at the limitation of drug choice and dose for the sedation nurse in the protocol (1 dose of oral triclofos sodium 100 mg/kg). However, this drug regimen proved to be effective in 93.5% of cases and safe in 99.8%. Midazolam, a benzodiazepine, could be an alternative drug for administration by the nurses, however. At a dose of 0.5 mg/kg, it was not found to be sufficient to perform procedures such as auditory brain stem response or visual evoked potentials-electroretinography. Propofol's sedation/hypnotic effect, fast onset, and extremely short duration made it very useful for sedation outside the operating room. Its antiemetic effects make it particularly useful for outpatient procedures. However, propofol may lead very quickly to deep sedation and airway obstruction, especially if is administered by clinicians with limited training and experience in its use. It should therefore be used only by practitioners such as anesthesiologists, who use it every day and who are able to manage any type of airway obstruction.

The most significant drawbacks of employing an anesthesiologist in a sedation service are increased costs and limited availability. Cost effectiveness was not assessed in this study. However, the absence of sedation failure, the reliability of the service, and the lack of complications when sedation/anesthesia was administered by a devoted service might all have defrayed the apparent costs. Finally, although not measurable directly in financial terms, there was a very high degree of patient and staff satisfaction with the sedation service.

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