Effect on Hospital-Wide Sedation Practices After Implementation of the 2001 JCAHO Procedural Sedation and Analgesia Guidelines

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Objective: To describe the effect of implementing the Joint Commission on Accreditation of Healthcare Organization's guidelines for procedural sedation and analgesia (PSA) on the frequency of adverse events occurring during sedation.

Design: Prospective, descriptive study.

Setting: Urban, tertiary care children's hospital.

Participants: Patients requiring PSA.

Interventions: A PSA committee and a standardized protocol for PSA were developed during a 6-month period. Institutional oversight was initiated to monitor practitioner compliance with the program. Data were abstracted from the sedation record.

Main Outcome Measures: The change in incidence of adverse events during PSA during the study. The strength of the association was determined by computing the Pearson product moment correlation.

Results: A total of 14,386 patients received PSA between July 1, 2001, and June 30, 2004. During the study, 7.6% of patients had an adverse event, with the most common being hypoxemia (39.7% of all adverse events). A trend toward a decrease in the incidence of adverse events was found during the study (Pearson product moment correlation, −0.68; P < 0.001).

Conclusions: Implementation of the 2001 Joint Commission on Accreditation of Healthcare Organizations guidelines for the provision of PSA appeared to lead to a decrease in the incidence of adverse events during the study. Implementation of uniform standards of monitoring and care for the provision of PSA may lead to safer conditions for pediatric patients undergoing PSA.

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Providing safe and effective sedation and analgesia in children to facilitate the successful completion of a procedure or study has been a topic of concern and regulation for several years. Before the widespread use of procedural sedation and analgesia (PSA), performing a procedure in a child often required the use of restraints and distraction. However, as diagnostic imaging has advanced and invasive pediatric procedures obviating the need for surgery have become more routine, the use of sedative, hypnotic, and analgesic drugs to perform such procedures has emerged as the practice of PSA.

Pediatric sedation practices evolved to meet the various needs of the pediatric procedure. Consequently, different practice standards, different definitions, different levels of monitoring, and different requirements for documentation and patient follow-up occurred within the same institution. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) recently implemented guidelines pertaining to PSA. These guidelines were designed to ensure that accredited institutions would provide uniform standards of monitoring and care within their institutions.1

Before the publication of the JCAHO guidelines, different departments within our institution (Children's Hospital of Pittsburgh) provided PSA according to their standards, with the result that each department provided PSA in different ways with differing degrees of monitoring and oversight. However, the JCAHO guidelines required that each department provide sedation by following a uniform standard. We hypothesized that, as a result, the incidence of adverse events occurring dur-
ing PSA would decrease across time. In this article, we report on the implementation of the JCAHO guidelines and a prospective evaluation of 3-year quality assurance data in patients undergoing PSA at the Children’s Hospital of Pittsburgh. We specifically sought to describe the incidence of adverse events that occurred during PSA, as well as changes in incidence across the study. In addition, this article details the educational process our institution went through in implementing the JCAHO guidelines. All data presented are from sedation events that occurred after implementation of the sedation program. This study was reviewed and approved by the institutional review board of Children’s Hospital of Pittsburgh.

METHODS

IMPLEMENTATION OF JCAHO GUIDELINES

Implementing the 2001 JCAHO guidelines at our institution required the following steps: program formation, program modifications, and program review.

PROGRAM FORMATION

The formation of a PSA committee and the development of a standardized protocol for pediatric sedation were conducted during a 6-month period. The development and implementation of the program proceeded in 3 distinct phases. The first phase involved identifying users of PSA within the hospital and forming a steering committee to articulate a uniform hospital policy. The second phase involved identifying all areas of the hospital where PSA took place, the equipment that was available, the personnel involved, and the practice standards in use. During the third phase of the program and with the use of the American Society of Anesthesiologists (ASA) guidelines for sedation for nonanesthesiologists and the 1992 American Academy of Pediatrics guidelines for pediatric sedation, the committee developed a single, unified practice standard. This unified sedation practice standard consisted of the following topics: defining sedation, presedation evaluation, dietary guidelines, equipment, monitoring standards, personnel and criteria for persons to be credentialed to administer sedation, documentation and development of a uniform sedation record, post-recovery standards, and discharge criteria.

The fourth step in the program involved implementing institutional oversight to monitor practitioner compliance with the program. Oversight ensured that all sedation records were completed by the physician and nursing personnel who provided sedation. The final aspect of the program involved data collection at each site that provided PSA and monthly meetings to discuss and review compliance and complications.

PROGRAM MODIFICATIONS

Throughout the 3-year quality improvement project, the hospital’s sedation committee met at monthly intervals to discuss issues pertaining to the implementation of the sedation program and to suggest modifications. Such modifications included the addition of a pain scale, the addition of provider “time-outs” (ie, break in clinical care to verify patient identity and correct patient for procedure), patient identification, surgical/procedure side-site verification (ie, verify correct site for procedure during the time-out), and providing all patients with supplemental oxygen during sedation.

PROGRAM REVIEW

After the development of a unified practice standard and a standardized record to document the presedation assessment, sedation process, recovery, discharge appropriateness, and complications, all PSA was monitored and all sedation records were reviewed during a 3-year period. All sedation records were reviewed prospectively, and adverse events that were not initially recorded by the medical personnel providing sedation were noted during this review. Administrative review was conducted within each department that provided sedation and ensured that all sedation events were recorded. Departments that did not comply with the sedation policy were no longer allowed to provide PSA to their patients.

A nurse involved with hospital quality improvement abstracted data from the standardized record forms. For compliance purposes, process variables were recorded as being present or absent on the basis of written documentation from the sedation reviews. Variables included nil per os status, age, weight, consent, ASA physical status, identification of the persons responsible for administering the sedation, identification of the persons responsible for monitoring the patient, patient condition at discharge, level of sedation, and medications used. Adverse events were defined as the occurrence of a complication noted on the sedation record and could be secondary to the procedure or to providing PSA. The following events were defined a priori: sustained hypoxemia (pulse oximetry of ≤90% for >1 minute), apnea, aspiration (evidence of respiratory distress and a new pulmonary infiltrate at chest radiography after sedation), vomiting, hypotension (sustained systolic blood pressure less than what is considered normal at the third percentile for age), bradycardia (heart rate less than what is considered normal at the third percentile for age), prolonged recovery (requiring >2 hours to recover to baseline status after administration of PSA), agitation related to pain, agitation unrelated to pain (paradoxical reaction or hallucinations), change in patient’s level of care (eg, hospital admission), and failed or inadequate sedation. Additional adverse events, including rash and hematoma, that occurred during sedation and were noted by health care personnel were recorded. The providers of PSA and the reviewers of the sedation records were familiar with the definitions of adverse events.

EFFECT OF SEDATION PROGRAM ON INCIDENCE OF ADVERSE EVENTS

Our main outcome measure for the sedation program was the change in incidence of adverse events during PSA. In particular, we hypothesized that the implementation of a hospital-wide sedation policy would result in a decrease across time in the incidence of adverse events during sedation.

STATISTICAL ANALYSIS

Clinical and demographic data are presented as means with standard deviations, medians, ranges, and proportions. The incidence of adverse events is presented as a proportion. The frequency of adverse events during each month of the study is presented graphically as a scatterplot (Figure). The strength of the association between the incidence of adverse events and study month was determined by computing a Pearson correlation with a 2-tailed significance of 93%. The null hypothesis was that no correlation would exist between the study month and the incidence of adverse events. The alternative hypothesis was that there would be a negative correlation between the study month and incidence of adverse events, thus suggesting that a standardized approach to sedation can reduce sedation-related adverse events.
RESULTS

During the 3-year study, 14,386 patients received PSA in the hospital between July 1, 2001, and June 30, 2004. The mean age of patients was 6.0 years (SD, 5.5 years; median age, 4 years; age range, 0.01-43 years). Three hundred forty-four patients (2.4%) were older than 18 years. Information pertaining to the sex and race of patients receiving PSA was not available for review. Information pertaining to ASA class was available for 10,626 patients (73.9%); 5415 (51.0%) patients were ASA class I, 4276 (40.2%) were ASA class II, 876 (8.2%) were ASA class III, and 59 (0.6%) were ASA class IV. Table 1 depicts the number of sedations provided in each unit of the hospital that provided PSA. Table 2 depicts the type and frequency of procedures that required PSA. The most common procedure to require PSA was magnetic resonance imaging (37.6%), followed by computed tomography (10.6%).

During the study, 1100 (7.6%) patients had an adverse event during sedation. Overall, there were 1289 adverse events, with some patients having more than 1 event. Patients who had an adverse event were significantly older than patients who did not (6.6 vs 5.9 years; P=.001). Table 3 depicts the type and frequency of adverse events during PSA. The most common adverse event was hypoxemia (39.7% [512/1289] of all events). Eighty-eight patients (0.6% [6.8% [88/1289] of all adverse events]) required transfer to a higher level of medical care because of an adverse event during PSA or because of concerns about patient vital signs or level of consciousness. Of these 88 patients, 22 had hypoxemia, 1 had nausea and vomiting, 2 had bradycardia, 3 had airway obstruction, 8 had prolonged sedation, 3 had agitation, 1 had bleeding, 1 had large amounts of secretions, and 1 had hypotension. Overall, 28 patients (0.2%) required the use of a reversal agent. Three of these 28 patients required transfer to a higher level of medical care. No patient required endotracheal intubation.
The frequency of adverse events during each procedure was documented. The most frequent occurrence of adverse events was cardiac catheterization (16.0%), needle aspiration (13.0%), and auditory brainstem response (13.0%). Table 4 depicts the frequency of adverse events within each medical unit providing PSA. The medical units with the most frequent occurrence of adverse events were the cardiac catheterization laboratory (16.3%) and the emergency department (11.7%).

Table 5 also depicts the frequency and type of sedation medications used during each PSA. The most common medication used for PSA was pentobarbital sodium (43.2%), alone or in combination with fentanyl citrate and midazolam hydrochloride, followed by the combination of fentanyl and midazolam (15.8%). Table 5 also depicts the frequency of adverse events according to type of sedation medication used. The medication regimens with the highest incidence of adverse events were the combination of ketamine hydrochloride, midazolam, and atropine sulfate (10.7%), followed by the combination of fentanyl and midazolam (9.7%). Table 6 presents the frequency of adverse events reported for each sedation regimen. Seventeen of the 28 patients who required the use of a reversal agent during sedation had received pentobarbital and fentanyl, 1 had received morphine and midazolam, 3 had received meperidine hydrochloride and midazolam, and 7 had received fentanyl and midazolam. No significant association was found between the type of medication used for sedation and the use of a reversal agent.

The Figure depicts the incidence of adverse events during each month of the study. A trend toward a decrease in the incidence of adverse events was noted during the study (Pearson correlation, -0.68; P < .001). Correlation was significant at the 0.01 level (2-tailed).

In this article, we focus on 1 institution’s experience when diverse groups of physicians are mandated to develop and comply with a unified standard for PSA. Previous studies about sedation primarily focused on various groups’ drug cocktails and their success and failure rates. Groups have ranged from individuals trained to provide sedation (eg, intensivists, emergency department physicians) to individuals providing sedation as an adjunct to their expertise (eg, gastroenterologists, radiologists). In this article, we view the development of a unified sedation policy from both administrative and patient safety perspectives.

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Administratively, the biggest challenge for the committee was to have the physicians who were providing PSA agree to actively participate in the creation, implementation, and monitoring of the hospital-wide sedation policy. The first hurdle for the sedation committee...
was to have them agree on definitions of what constituted PSA. Although JCAHO regulations introduced the terms anxiolysis, moderate sedation/analgesia, deep sedation/analgesia, and general anesthesia, our committee decided that PSA represented a continuum of patient responsiveness and that the individuals who administered PSA needed to have the skills to rescue patients from the deepest level of sedation. Consequently, the committee determined that we would use the term procedural sedation in reference to all sedation events. In addition, the committee decided that all individuals directing sedation must have completed a hospital course for sedation or be certified in pediatric advanced life support, advanced cardiac life support, or be certified in pediatric advanced life support, atropine as atropine sulfate; meperidine as meperidine hydrochloride; and morphine as morphine sulfate.

Table 6. Frequency of Adverse Events According to Type of Sedation Regimen*

<table>
<thead>
<tr>
<th>Drug Group</th>
<th>Aspiration</th>
<th>Vomiting</th>
<th>Hypoxemia</th>
<th>Bradycardia</th>
<th>Airway Obstruction</th>
<th>Prolonged Sedation</th>
<th>Agitation Related to Pain</th>
<th>Agitation Unrelated to Pain</th>
<th>Hypotension</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlorhydrate (n = 2088)</td>
<td>0</td>
<td>16 (0.6)</td>
<td>49 (2.4)</td>
<td>0</td>
<td>1 (0.05)</td>
<td>20 (1.0)</td>
<td>1 (0.05)</td>
<td>5 (0.2)</td>
<td>4 (0.2)</td>
</tr>
<tr>
<td>Pentobarbital (n = 6219)</td>
<td>0</td>
<td>26 (0.4)</td>
<td>207 (3.3)</td>
<td>5 (0.08)</td>
<td>5 (0.08)</td>
<td>90 (1.4)</td>
<td>100 (1.6)</td>
<td>40 (0.6)</td>
<td>4 (0.06)</td>
</tr>
<tr>
<td>Nitrous oxide (n = 831)</td>
<td>0</td>
<td>6 (0.7)</td>
<td>2 (0.2)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Ketamine, midazolam, atropine (n = 1010)</td>
<td>0</td>
<td>15 (1.5)</td>
<td>36 (3.6)</td>
<td>0</td>
<td>1 (0.1)</td>
<td>42 (4.2)</td>
<td>0</td>
<td>0</td>
<td>1 (0.1)</td>
</tr>
<tr>
<td>Ketamine, atropine (n = 532)</td>
<td>0</td>
<td>10 (1.9)</td>
<td>11 (2.1)</td>
<td>0</td>
<td>1 (0.2)</td>
<td>19 (3.6)</td>
<td>1 (0.2)</td>
<td>0</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td>Morphine, midazolam (n = 199)</td>
<td>0</td>
<td>0</td>
<td>11 (5.5)</td>
<td>0</td>
<td>0</td>
<td>1 (0.5)</td>
<td>0</td>
<td>0</td>
<td>1 (0.5)</td>
</tr>
<tr>
<td>Meperidine, midazolam (n = 346)</td>
<td>0</td>
<td>0</td>
<td>6 (1.7)</td>
<td>0</td>
<td>0</td>
<td>1 (0.3)</td>
<td>0</td>
<td>3 (0.9)</td>
<td></td>
</tr>
<tr>
<td>Fentanyl, midazolam (n = 2267)</td>
<td>0</td>
<td>9 (0.4)</td>
<td>162 (7.1)</td>
<td>3 (0.1)</td>
<td>8 (0.4)</td>
<td>15 (0.7)</td>
<td>2 (0.1)</td>
<td>1 (0.04)</td>
<td>22 (1.0)</td>
</tr>
<tr>
<td>Midazolam (n = 600)</td>
<td>0</td>
<td>1 (0.2)</td>
<td>18 (3.0)</td>
<td>1 (0.2)</td>
<td>0</td>
<td>4 (0.7)</td>
<td>1 (0.2)</td>
<td>2 (0.3)</td>
<td>5 (0.8)</td>
</tr>
</tbody>
</table>

*Data are given as number (percentage). Not all adverse events are included in the table. Only the most frequently used sedation regimens are included. No patient had an episode of aspiration. Pentobarbital was given as pentobarbital sodium; midazolam as midazolam hydrochloride; ketamine as ketamine hydrochloride; atropine as atropine sulfate; meperidine as meperidine hydrochloride; and morphine as morphine sulfate.

ord appropriately and documented all required information. As an example, during the study, ASA classification was documented in only 73.9% of patients. However, documentation of ASA classification improved during the study as practitioners (predominantly nonanesthesiologists) became more familiar with the concept. Similarly, practitioners became more compliant with documenting other unfamiliar items, such as side-site and procedure time-outs, as the study progressed. Items or concepts that practitioners were more familiar with, such as the documentation of adverse events, were documented appropriately from the beginning of the study. Thus, we believe that all, or nearly all, sedation events and adverse events were captured during the study.

We documented a trend toward a decrease in the incidence of adverse events during sedation provided at our institution. Reports of adverse events related to institutional sedation programs are scant. In a hospital-wide study of 1140 children sedated for a wide variety of procedures, Malviya et al4 reported a 20% incidence of adverse events, with inadequate sedation occurring in 13.2% of patients and hypoxemia in 5.5%. In contrast to our study, in which we noted adverse events in older children, Malviya et al noted that an age younger than 1 year and an ASA class of III or IV were independent risk factors for adverse events. In a study of 1014 pediatric patients undergoing PSA in the emergency department, Agrawal et al5 also noted that adverse events were associated with children of older age and deeper levels of sedation.

Hypoxemia and failed sedation tend to be the 2 most common adverse events in pediatric sedation. Although the incidence of hypoxemia in pediatric PSA studies varies widely, transient hypoxemia generally has no lasting sequelae.6,7,9 Hypoxemia probably is related to the increased propensity for the pediatric airway to become obstructed. In our study, hypoxemia was a common event that generally responded to airway manipulation (jaw thrust, oral airway placement, repositioning the patient’s head) and the use of supplemental oxygen.

Failed sedation probably occurs because of the difficulty of providing adequate sedation while maintaining
adequate respiration. Failed sedation has financial and patient/parent satisfaction implications. In a study in which children undergoing sedation were compared with those receiving general anesthesia, Malviya et al\(^9\) noted that the incidence of inadequate sedation was 16% and failed sedation was 7%. In a study of children sedated with pentobarbital for magnetic resonance imaging, Greenberg et al\(^10\) noted that the failure rate was 8% and that sedation was more likely to be successful in children older than 11 years. Causes of failed sedation are multiple. Karian et al,\(^11\) in a study of children undergoing radiological procedures, reported a 7% sedation failure rate and found that only the type of sedation medication used was a predictor of failure. In a report in which the relationship of temperament and sedation failure was evaluated for magnetic resonance imaging and computed tomography, Voepel-Lewis et al\(^12\) noted that children whose sedation failed were less adaptable than those children whose sedation was successful.

Not surprisingly, the radiology department provided nearly half of all sedation during the study. Typically, medical procedures such as magnetic resonance imaging and computed tomography require PSA in the younger child. However, the medical unit with the highest proportion of adverse events was the cardiac catheterization laboratory, which may be related to the fact that children undergoing cardiac catheterization are more likely to have a serious medical problem, require deeper levels of sedation and analgesia, or may receive different medications than children undergoing magnetic resonance imaging or computed tomography.

This study was designed to look at all patients sedated at our institution, regardless of age. Interestingly, 2.4% of all patients sedated in the hospital were older than 18 years. Most of these patients had a history of a chronic medical condition and had received care at our institution for several years. However, they were sedated at a pediatric institution, often by physicians trained to treat children. As a result, health care personnel who provide sedation at our institution are expected to be prepared to sedate both the pediatric and the adult patient.

There are several limitations to this study. The physicians providing PSA were aware that the committee would be closely monitoring the use of PSA in the hospital. As a result, physicians may have adapted their behavior to reduce the occurrence of adverse events. Because monitoring of sedation will continue, this change in behavior would be of continued benefit. In addition, the physicians and nurses involved in PSA may have altered their recording of adverse events in an effort to decrease their department’s incidence of adverse events. Finally, the level of training and clinical experience of the physicians providing PSA and the types of medications used during PSA most likely varied substantially among the medical units providing PSA, making direct comparisons difficult. In addition, patients were not randomly assigned to receive the various medications, thus limiting comparisons among sedation regimens.

CONCLUSION

We believe that the implementation of a standardized, hospital-wide protocol for PSA, along with the establishment of a PSA committee that provides close scrutiny and evaluation of the sedation program within an institution, may lead to a marked hospital-wide decrease in the incidence of adverse events during PSA. To our knowledge, this is the first study that has looked at the potential effect of the 2001 JCAHO guidelines on providing PSA within an institution. Additional studies may confirm the potential benefit of adopting the JCAHO guidelines.

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