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Pediatrics 2002;109;236-243
DOI: 10.1542/peds.109.2.236

Risk Reduction in Pediatric Procedural Sedation by Application of an American Academy of Pediatrics/American Society of Anesthesiologists Process Model

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ABSTRACT. *Objective.* **Guidelines for risk reduction during procedural sedation from the American Academy of Pediatrics (AAP) and the American Society of Anesthesiologists (ASA) rely on expert opinion and consensus. In this article, we tested the hypothesis that application of an AAP/ASA-structured model would reduce the risk of sedation-related adverse events.**

Methods. **Prospectively coded sedation records were abstracted by a hospital quality improvement specialist with practical and administrative experience in pediatric sedation. Process variables included notation of nulla per os (NPO) status, performance of a guided risk assessment, assignment of ASA physical status score, obtaining informed consent, generation of a sedation plan, and assessment of sedation level using a quantitative scoring system. Content variables included adherence to AAP NPO guidelines, ASA class, target sedation level, actual sedation level, age, procedure, and drugs used. Complication risk was assessed by logistic regression and Mantel-Haenszel odds ratios (OR).**

Results. **Complications were identified in 40 of 960 records (4.2%). The complication rate was 34 of 895 (3.8%) with planned conscious sedation and 6 of 65 (9.2%) with planned deep sedation ([DS]; OR: 2.6). Complications were reduced by performance of structured risk assessment (OR: 0.10), adherence to all process guidelines (OR: 0), and avoiding actual DS (OR: 0.4). The only drug associated with higher risk was chloral hydrate (OR: 2.1). Failure to adhere to NPO guidelines did not increase risk in this assessment; however, the adverse event rate was 0 if all process guidelines were followed.**

Conclusions. **Presedation assessment reduces complications of DS. Repeated assessment of sedation score reduces the risk of inadvertent DS. The data provide direct evidence that AAP/ASA guidelines can reduce the risk of pediatric procedural sedation.** ***Pediatrics*** **2002;109: 236–243;** ***sedation, analgesia, conscious sedation, procedural sedation, deep sedation, adverse events, patient safety, practice guidelines, anesthesia.***

ABBREVIATIONS. AAP, American Academy of Pediatrics; ASA, American Society of Anesthesiologists; NPO, nulla per os; DS, deep sedation; CS, conscious sedation; GRA, guided risk assessment; OR, odds ratio; CI, confidence interval.

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Received for publication Apr 20, 2001; accepted Sep 19, 2001.

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The administration of sedative-analgesic medication can enhance the comfort and acceptance of diagnostic and therapeutic procedures in children[1–3] but can also produce serious, potentially life-threatening, adverse effects.[3–10] The universal application of practice standards has reduced the risk of serious complications associated with general anesthesia in the past 2 decades[11,12] by addressing procedural,[12–15] equipment,[12,16,17] and human[13,18,19] factors related to errors and adverse events. The American Academy of Pediatrics (AAP),[4,5] American Society of Anesthesiologists (ASA),[6] Joint Commission on Accreditation of Healthcare Organizations,[20,21] and other professional bodies[22–24] have published standards statements in attempts to enhance the safety of procedural sedation by standards application. However, because these standards are based largely on expert opinion,[6,20] are not mutually consistent,[7,20] and explicitly restrict practice, they have not been uniformly accepted, adopted, or applied. Actual risk reduction by any process for procedural sedation other than comparison to historical controls[20] has not been reported to our knowledge.

We structured a program for pediatric procedural sedation by nonanesthesiologists using a model based on ASA and AAP guidelines. Essential components of this program included personnel and monitoring standards (including a separate clinician for patient sedation and assessment, and universal pulse oximetry), a guided presedation risk assessment, nulla per os (NPO) guidelines, a sedation scoring system, time-based recordings of sedation status and vital signs in a standardized format, monitored recovery until awake, and assessment of fitness for discharge. At implementation, several controversies were unanswered, including whether deep sedation (DS) carried higher risk, whether NPO guidelines reduced risk, and whether any aspects of a structured approach would affect risk at all. In this analysis, we examined the hypothesis that application of a structured model to the practice of procedural sedation would reduce the occurrence of adverse events.

METHODS

A policy for a uniform sedation process was implemented at Children's Hospital of Wisconsin in July 1998. The key components of this model, summarized in Table 1, were derived from guidelines published by the AAP for pediatric sedation[4] and by the ASA for sedation by nonanesthesiologists.[6] A guided assessment tool was developed to assist in identification of specific conditions that confer increased sedation risk, which are listed in Table 2. A quantitative sedation score was used to gauge the depth of sedation, with anchors to delineate boundaries between "conscious" sedation (CS) and DS along a sedation continuum (see Table 3). A standardized record was used to document the presedation assessment, sedation process, recovery, discharge readiness, and complications.

A comprehensive, focused review of all sedation records during a 3-month period from July to October 1999 was used for this analysis. A hospital quality improvement specialist with practical and administrative experience in pediatric sedation abstracted data from the standardized records for documentation of adherence to selected aspects of the sedation process and for the presence of putative risk factors for sedation. Process variables were abstracted as present or absent on the basis of documentation on the respective section of the sedation record. Process variables included performance of a guided risk assessment (GRA), notation of NPO status, assignment of ASA risk classification, obtaining informed consent, generation of a sedation plan, and regular assessment of sedation depth using a structured assessment and scoring system. Content variables were coded on the basis of all available data on the sedation record and in the patient chart. Content variables included adherence to AAP NPO guidelines,[4] ASA physical status score, target sedation level, actual sedation level, age, procedure, and type and number of drugs used. DS was coded when the actual sedation score was <4 at any time during the procedure.

The primary outcome measure was the occurrence of any complication or adverse event reported on the sedation record or through universal quality improvement screening. The sedation record prompted for specific adverse events, including inadequate or failed sedation, sustained hypoxemia (10% below baseline), airway obstruction (requiring airway adjunct or sustained jaw lift maneuver), apnea, aspiration, hypotension, bradycardia, prolonged or excessive sedation, and other. Complications were segregated into categories: type 1, suggestive of inadequate sedation, and type 2, suggestive of physiologic side effect or adverse event. A severity score was assigned to complications on the basis of patient outcome.

The relationship of components of the sedation process to the incidence of complications was assessed in univariate and multivariate models. All process and content variables were entered into a logistic regression model, with stepwise rejection of factors at $P > .2$. Factors retained in this model were then used to adjust univariate Mantel-Haenszel odds ratios (OR) calculated for each factor, with and without stratification by sedation plan. Binomial exact 95% confidence intervals (CI) are reported in addition to point incidence rates when appropriate. Significance was assessed by χ^2 and trend tests, and interactions were tested using N-way analysis of variance, with cutoff for significance at $P < .05$. Factor analysis was used to identify covariance patterns. All calculations were performed with Stata statistical software (Stata Corp, College Station, TX).

TABLE 1. Components of the Children's Hospital of Wisconsin Sedation Model

Monitoring and personnel requirements
NPO guidelines from the AAP[5]
Presedation evaluation
Focused present and past history
Focused physical examination
Vital signs
GRA
Assignment of ASA physical status score
Generation of sedation plan
Informed parental consent
Equipment/monitoring standards based on actual level of sedation
Quantitive sedation scoring
Time-based recording of vital signs, oxyhemoglobin saturation, and sedation level
Recovery and discharge criteria
Standardized record

Essential components of the CHW structured sedation program, adapted from ASA and AAP guidelines. Each of these components is specifically prompted on a uniform sedation documentation record.

TABLE 2. Sedation GRA Tool

Sedation Risk Factors
Snoring, stridor, or sleep apnea
Craniofacial malformation
History of airway difficulty
Vomiting, bowel obstruction
Gastroesophageal reflux
Pneumonia or oxygen requirement
Reactive airways disease
Hypovolemia, cardiac disease
Sepsis
Altered mental status
History of sedation failure
Inadequate NPO time
No identified risk factors

Patient conditions with potential to affect risk of sedation are specifically prompted on the sedation record. These conditions composed the GRA element of the sedation process.

RESULTS

Complete abstraction of procedural sedation records yielded 960 records during the study period. Age was <2 years in 508 (53%) patients, and the ASA physical status score was 1 or 2 in 854 (89%; see Table 4 for details). The sedation plan was CS or unspecified in 895 (93%) and DS in 65 (7%); however, DS was actually achieved in 215 (22%). Table 5 shows the distribution of procedures and actual sedation type by service. Adverse events or complications were identified in 40 (4.2%) sedation procedures overall, detailed in Table 6. No adverse events were noted beyond the immediate recovery period.

The occurrence of complications was related to both the target and actual levels of sedation. The complication rate was 34 of 895 (3.8%; 95% CI: 2.6%–5.3%) with planned CS, and 6 of 65 (9.2%; 95% CI: 3.4%–19.0%) with planned DS (OR: 2.6; $P = .034$). The complication rate was 28 of 745 (3.8%; 95% CI: 2.5%–5.4%) in patients who actually remained conscious and 12 of 215 (5.6%; 95% CI: 2.9%–9.5%) in patients who were actually deeply sedated ($P = .24$). Inadvertent DS (165 of 895 [18%]) during planned CS did not increase the rate of complications (6 of 165 [3.6%]; 95% CI: 1.3%–7.7%). However, patients who achieved DS as planned (50 of 65 [77%]) had the highest complication risk (6 of 50 [12%]; 95% CI: 4.5%–24.3%; OR: 3.6; $P = .024$). The lowest risk was observed in patients in whom DS was targeted but who actually received CS (0 of 15; 95% CI: 0%–21.8%; OR: 0; $P = .024$; see Fig 1). Type 2 complications, reflecting physiologic deterioration, accounted for all excess risk with DS.

Performance of GRA significantly reduced the complication rate in the logistic model (OR: 0.50; $P = .041$). After stratification by target sedation plan, complications were reduced by performance of GRA (OR: 0.10; $P = .018$), by adherence to all process

TABLE 3. The Children's Hospital of Wisconsin Sedation Scale

Sedation Classification	Sedation Score	Description
Inadequate	6	Anxious, agitated, or in pain
Minimal–conscious	5	Spontaneously awake without stimulus
Conscious–moderate	4	Drowsy, eyes open or closed, but easily arouses to consciousness with verbal stimulus
Moderate–deep	3	Arouses to consciousness with moderate tactile or loud verbal stimulus
Deep	2	Arouses slowly to consciousness with sustained painful stimulus
	1	Arouses, but not to consciousness, with painful stimulus
Anesthesia	0	Unresponsive to painful stimulus

The CHW sedation scale was modified from the Ramsay[37] scale to provide additional behavioral anchors in the useful range of moderate sedation. The CHW sedation guidelines call for assessment of sedation depth by quantitative score every 5 minutes until a sedation score of 4 or greater is achieved postprocedure. Patients with sedation scores of 4–5 were classified as having received CS; those with scores of 3 or less were classified as having received DS.

TABLE 4. Age and ASA Physical Status of Patients

Age	*n*	ASA	*n*
0–1 mo	41	1	501
1–6 mo	149	2	353
6–12 mo	138	3	56
1–2 y	180	4	14
2–5 y	239	5	2
>5 y	212	6	0

guidelines (OR: 0; $P = .047$), and in patients who avoided DS levels (OR: 0.4; $P = .04$). Neither age nor ASA physical status was predictive of complications in this analysis. A summary of risk factors in univariate and multivariate models is presented in Table 7.

The safety effect of GRA performance was most apparent in patients who underwent targeted DS (Fig 2), in which the complication rate was reduced by 90%, from 17% (95% CI: 6.6%–33.6%) to 1.7% (95% CI: 0.04%–8.9%; OR: 0.1; $P < .018$). This safety factor was also observable in all patients who achieved DS regardless of plan, from 9.1% (95% CI: 4.2%–16.7%) to 2.6% (95% CI: 0.5%–7.4%; OR: 0.27; $P = .04$; Fig 3). The progressive increase in risk at deepest sedation levels and the salutary effects of presedation risk assessment on the occurrence of adverse events is shown in Fig 4.

The risk of adverse event increased with the number of drugs administered (1 drug: 17 of 642 [2.7%]; 2 drugs: 15 of 250 [6.0%]; OR: 2.27; 3 drugs: 8 of 55 [14.5%]; OR: 5.49; $P < .01$). The only drug associated with higher risk in univariate analysis was chloral hydrate (OR: 2.1; $P = .041$), even when used as the sole sedative agent and after adjusting for target sedation level. Chloral hydrate was the only medication associated with inadvertent DS (OR: 11.6; $P < .0001$) when used alone. Unintended DS with multiple drugs was significantly more likely with chloral hydrate (OR: 8.1; $P < .0001$), fentanyl (OR: 5.1; $P = .016$), or ketamine (OR: 5.7; $P < .0001$). In the multivariate model, chloral hydrate, pentobarbital, fentanyl, and ketamine were each associated with higher complication rate (see Table 7). Conversely, midazolam was associated with a lower than average complication rate (OR: 0.17; $P = .042$) in univariate and multivariate analysis, and no complications were reported with midazolam monotherapy. The adverse event rate for all medications used is shown in Fig 5.

AAP NPO criteria were not met in 309 of 960 (32%) patients, and in 45 of these (15%), NPO status was not documented before sedation. Adherence to NPO guidelines did not affect overall risk of complications (11 of 309 [3.6%]; 95% CI: 1.8%–6.2% vs 29 of 651 [4.5%]; 95% CI: 3.0%–6.3%; OR: 0.79; $P = .64$) and did not decrease the risk of type 2 complications in this assessment (9 of 309 [2.9%]; 95% CI: 1.3%–5.5% vs 18 of 651 [2.8%]; 95% CI: 1.6%–4.3%; OR: 0.97; NS). The complication risk was insignificantly different in patients without documented NPO status (3 of 45 [6.7%]; 95% CI: 1.4%–18.3% vs 37 of 915 [4.0%]; 95% CI: 2.9% –5.5%; OR: 1.68; $P = .43$). However, the occurrence of type 1 complication (sedation failure) was significantly higher in patients who met NPO criteria (20 of 921 [2.2%]; 95% CI: 1.3%–3.3% vs 2 of 443 [0.5%]; 95% CI: 0.05%–1.6%; OR: 4.4; $P = .016$). Sedation failure was equally observed both in targeted CS and targeted DS.

DISCUSSION

The purpose of this study was to assess the effect of AAP/ASA practice guidelines on the safety of pediatric procedural sedation. Although all data were recorded prospectively, the observational nature of the study limited the comparisons to cohorts derived by retrospective analysis of data. We did not think that arbitrarily constraining practice or randomly assigning patients to deep or light sedation plans would be safe or ethical given the range of sedation needs, locations, providers, and patients in a tertiary children's hospital. Inspection of the data revealed that significant variation in practice was occurring, and this variation allowed the comparisons on which our conclusions are drawn. Although variation in compliance with the sedation process might have affected the reporting of actual complications, this bias would have resulted in a higher complication rate in patients with more complete documentation of process. In fact, the opposite relationship was observed.

The primary finding of this study was that adherence to guidelines for a structured process for pediatric procedural sedation reduced the occurrence of adverse events. This finding is consistent with the observed reduction in adverse events during anesthesia by the adoption of relatively uniform practice and monitoring guidelines.[11–14,18,19] Although the risk of physiologic deterioration without active intervention may be higher in patients who undergo general anesthesia, the differences between induction of

TABLE 5. Procedures by Service

Service	Total	% Deep	Procedures
Cardiology	176	66%	Echocardiogram, cardiac catheterization
Cardiothoracic surgery	21	19%	Chest tube removal, PICC line placement
Dental	23	0%	Cleaning and restoration
Emergency medicine	49	31%	Suture laceration, aspiration, closed reduction
Gastroenterology	3	33%	Liver biopsy
General surgery	45	0%	Burn dressing change, line placement
Hematology/oncology	25	0%	Bone marrow aspiration/biopsy, lumbar puncture
Nephrology	12	0%	Kidney biopsy
Neurology	10	0%	Electroencephalogram
Orthopedic surgery	18	11%	Closed reduction, aspiration
Pulmonary	25	88%	Pulmonary function test, bronchoscopy
Radiology	520	10%	Bone scan, CT scan, MRI scan
Other	27	16%	Examination, line placement

CT indicates computed tomography; MRI, magnetic resonance imaging; PICC, peripherally inserted central catheter.

TABLE 6. Complications

Category	Description	*n*
Type 1	Inadequate sedation	5
	Sedation failure	8
Type 2	Sustained hypoxemia (<92% or 6% below baseline)	9
	Airway obstruction requiring intervention	5
	Apnea	3
	Aspiration	2
	Hypotension or bradycardia	2
	Prolonged or excessive sedation	6
Severity score		
0	No complication or process variation	3
1	Minimal complication without process variation	11
2	Minimal process variation	15
3	Care escalation	11
4	Temporary injury	0
5	Permanent injury	0
6	Death	0

The classification and severity of complications as prompted on the sedation record. Sedation failure was defined by failure to complete the procedure. All complications were identified during the sedation and recovery process. Minimal complications without process variation typically included hypoxemia requiring airway support or inadequate sedation with delays. Process variations included calls for help, prolonged recovery, and procedure abandonment. Care escalation involved transfer of service, placement in intensive care, or unintended overnight monitoring or treatment intensification. No permanent injuries were identified.

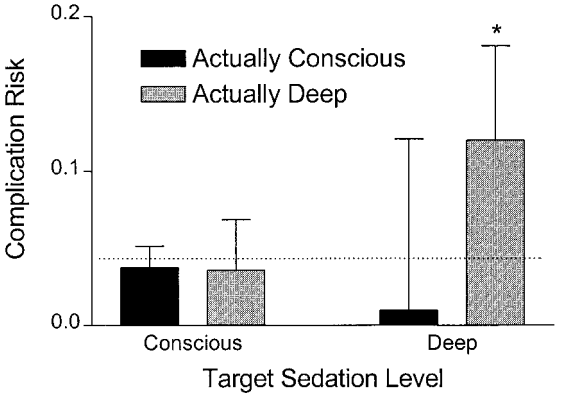

Fig 1. The effect of achieved depth of sedation on frequency of adverse events (risk point estimate and 95% CI) according to target sedation level. The dotted line marks the overall complication rate of 3.8%. The risk was significantly elevated when targeted DS was achieved (risk = 12%; *P = .046 for interaction).

procedural sedation and induction of general anesthesia are evident only by degree of behavioral and physiologic effect observable in retrospect. In this light, it would actually be surprising if process guidelines did not reduce risk for procedural sedation.

The process element most important for risk reduction was use of the guided risk assessment tool. The content of this risk assessment was drawn from the opinion of the authors and known risk factors for physiologic deterioration, particularly obstructed breathing[25,26] for which snoring is a marker. Although this study does not have adequate power to determine which specific elements of the GRA tool were associated with risk, our analysis indicates that such a guided assessment is important for identifying patients who are at risk for sedation by practitioners with diverse practice specialties and experience. Failure to complete this risk assessment was the single most important predictor of adverse events during DS. Performance of risk assessment also reduced the risk of excessively deep sedation (sedation score <2). Performance of GRA showed the most uniqueness in factor analysis and was the only process element significant in all statistical analyses, suggesting that use of the tool, not just careful documentation, altered risk.

Our analysis revealed that planned deep levels of sedation carried a higher risk of adverse event than planned light, or "conscious," sedation. Although the border between CS and DS is arbitrary, the high rate (18%) of actual DS in patients with planned CS illustrates both the unpredictability of the sedation process and the tendency to underrate the anticipated sedation target. The term "conscious sedation" may be used as an inappropriate euphemism for unreported DS[9,27] in an attempt to minimize the risk of physiologic trespass or adverse event. This finding is of special relevance for sedation of infants and children, in whom induction of unconsciousness is frequently required to facilitate even nonpainful procedures. Adverse events in our database were most commonly observed during nonpainful procedures such as diagnostic imaging studies and pulmonary function tests. Our overall adverse event rate was similar to or less than that reported in other studies,[3,10,28–34] and the risk rate in patients with adequate presedation assessment was comparable to the

TABLE 7. Factors That Predict Complications

Element	Frequency	Logistic OR (*P*)	Univariate OR (*P*)	Stratified OR (*P*)	Stratified and Adjusted OR (*P*)
Process variables					
GRA	49.9%	0.50 (.041)	0.52 (.034)	0.10 (.018)	0.10 (.02)
ASA status assignment	71.9%	3.40 (.029)	3.28 (.047)	—	—
Sedation plan	87.4%	4.18 (.176)	—	—	—
NPO documentation	95.3%	—	0.45 (.19)	.45 (.19)	—
Sedation scoring	62.0%	—	—	—	—
Consent documentation	70.0%	—	—	—	—
Content variables					
Actual deep level	22.4%	1.8 (.011)	—	9.9 (.16)	9.8 (.18)
NPO criteria met	71.1%	—	—	9.0 (.16)	9.8 (.14)
Target deep level	17.4%	—	2.51 (.034)	—	
Medications administered					
Three or more drugs	5.7%	3.2 (.001)	3.58 (.001)	—	—
Chloral hydrate	15%	5.3 (.006)	2.1 (.041)	2.45 (.018)	2.13 (.036)
Midazolam	28%	0.21 (.014)	0.17 (.042)	0.21 (.086)	0.22 (.048)
Fentanyl	1.0%	11.3 (.04)	—	—	—
Pentobarbital	28%	3.2 (.02)	—	—	—
Ketamine	2.8%	4.5 (.09)	—	—	—

OR for complications according to the presence or absence of process elements and their content, and corresponding *P* values, are shown if $P < .20$. Logistic OR, beginning with a full model, stepwise logistic regression with rejection at $P > .2$ identified 10 factors that affect risk; univariate OR, simple Maentel-Haenszel OR for each factor; stratified OR, OR stratified by target sedation level; stratified and adjusted OR, OR stratified and adjusted for GRA, ASA, sedation plan, and actual depth.

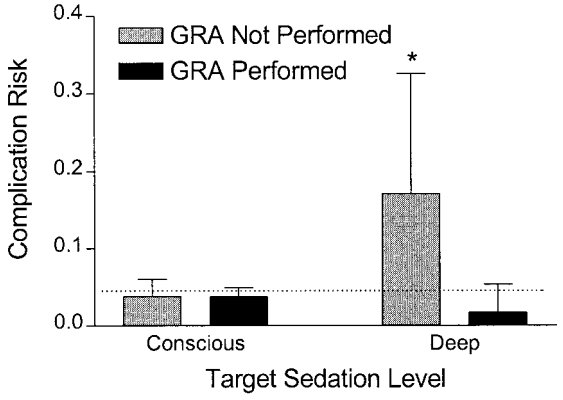

Fig 2. The effect of presedation GRA on frequency of adverse events (risk point estimate and 95% CI) according to target sedation level. The dotted line marks the overall complication rate of 3.8%. Performance of GRA significantly reduced the complications of DS from 17% to 1.7% (*$P = .007$ for interaction).

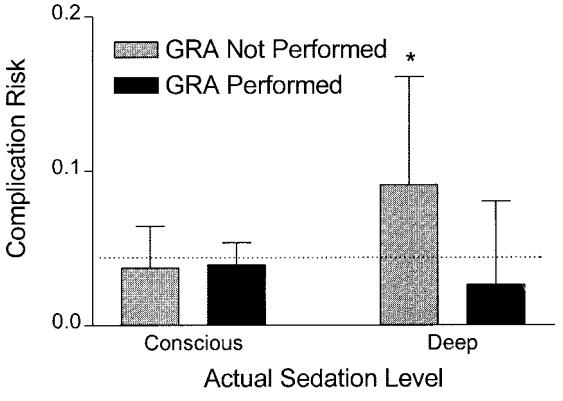

Fig 3. The effect of presedation GRA on frequency of adverse events (risk point estimate and 95% CI) according to actual sedation level. The dotted line marks the overall complication rate of 3.8%. Performance of GRA significantly reduced the complications of DS from 9.9.% to 2.1% (*$P = .037$ for interaction).

lower rate of adverse events in patients who underwent general anesthesia versus DS for endoscopy[25,28] or magnetic resonance imaging.[3,29,35] However, the validity of comparison of event rates across practice settings may be limited without careful matching of patients, procedures, and the availability of trained specialists as rescue personnel.

The use of quantitative scoring provides some standardization in terminology and classification of sedation depth. Many sedation scales have been used to guide administration of sedative drugs,[36] but none has been advocated as an essential part of the practice of procedural sedation. The Children's Hospital of Wisconsin scale has several anchors between hyperarousal and complete unresponsiveness. These anchors were added during the development of the sedation scale, before the study period, because we experienced limitations in the applicability of the Ramsay scale[37] to the range of sedation commonly used. The progressive increase in complications observed with deeper actual levels of sedation (Fig 4) confers validity to the scale for identification of patients at higher risk of complication.

The finding that risk reduction by adherence to guidelines was most evident among patients at lowest actual sedation scores (Fig 4) emphasizes the concept of a linked sedation and risk continuum. Administration of medications guided by current patient status to achieve a desired sedation endpoint requires some method of quantification of sedation depth along the continuum from hyperarousal to the state of autonomic and behavioral hyporesponsiveness characteristic of general anesthesia. We attribute the safety of inadvertent DS observed in this review to the use of sedation scoring, which facilitates the identification of excessive sedation before serious physiologic side effect occurs.

The relatively high rate of adverse events observed with chloral hydrate contrasts with widespread perceptions about its safety.[38] This high risk persisted

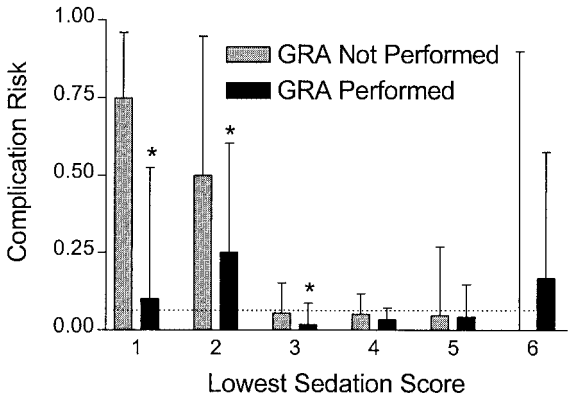

Fig 4. The frequency of adverse events (risk point estimate and 95% CI) by actual lowest sedation score and the effect of performance of GRA. The dotted line marks the overall complication rate of 3.8%. The frequency of adverse events increased with lower sedation scores ($P = .022$ test for trend), and performance of GRA reduced risk for sedation scores of 3 or less (*$P < .05$ compared with risk without GRA).

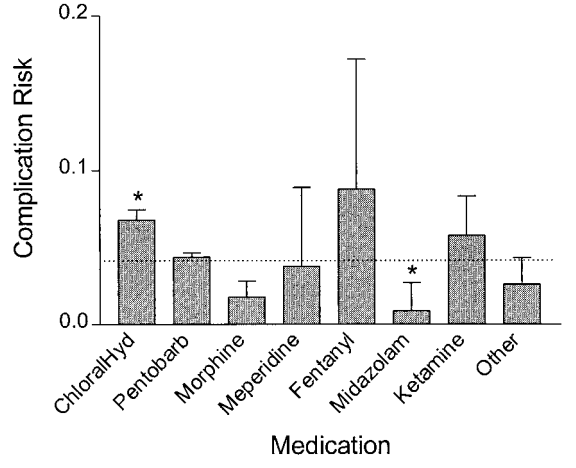

Fig 5. The frequency of adverse events by medications administered (risk point estimate and 95% CI), adjusted for target and actual sedation level and total number of medications used. The adverse event rate was significantly higher for chloral hydrate (OR: 2.13) and lower for midazolam (OR: 0.22; *$P < .05$),

after adjustment for target sedation level, type of procedure, and ASA status and in multivariate analysis. The types of complications observed with chloral hydrate included hypoxemia, hypotension, and overt airway obstruction. These potentially life-threatening complications were observed despite typical dosing at 50 to 75 mg/kg, even when chloral hydrate was used as a sole agent for hypnosis. Chloral hydrate was the most common cause of inadvertent DS, emphasizing continuing underappreciation of its potent hypnotic effects and risk.[8] This finding underscores the inherent danger of unconscious sedation and the interaction of unconsciousness on respiratory function regardless of specific cause.[25,26,39,40]

A lower-than-average rate of adverse events was observed with midazolam, a drug that seldom causes unconsciousness in children when used alone, even in huge doses for anesthesia induction.[41] Even after adjustment for the actual level of sedation, the safety differences between midazolam and chloral hydrate were still statistically significant. Patient acceptance of procedures is higher[1,2] and adverse events lower[1,42,43] with midazolam than with opioids or opioid-hypnotic combinations.

Although the highest complication rate occurred with fentanyl, this drug was rarely used as the sole agent, and its infrequent use did not permit statistically valid conclusions to be drawn from our sample. Combinations of 3 or more drugs had a higher complication rate, as previously reported.[8,42] However, polypharmacy was highly associated with planned and achieved DS, and the excess risk of polypharmacy disappeared after adjustment for sedation level. Nonetheless, the data reinforce the previously reported risks of opioid-sedative combinations, particularly fentanyl.[43]

The effect of NPO status on sedation outcome could not be adequately assessed in this study because inadequate NPO time was identified a priori as a risk factor, which should have altered the sedation plan. Evidence that knowledge of NPO status altered sedation process includes the finding of a trend toward a lower rate of actual DS in patients not adequately NPO (5.1% vs 8.3%; $P = .10$), reflecting a more cautious approach to medication administration for non-NPO patients, regardless of the planned level of sedation. Alternatively, as suggested by practitioners who are opposed to NPO guidelines, sedation of infants and young children may be more difficult when they are hungry. Documentation of NPO status was present in 62 of 65 patients who underwent planned DS, but no complications were observed in the 3 patients with undocumented NPO status. We interpret this as evidence that practitioners used data appropriately to avoid DS in non-NPO patients. The 2 aspiration events occurred in patients who met NPO criteria and were deeply sedated with opioid-barbiturate combinations, 1 for a radiologic procedure, the other for bronchoscopy; these patients required postprocedure care escalation by overnight oxygen administration. The aspiration incidence was thus 3.1% (95% CI: 0.37%–10.7%) of patients who were deeply sedated or 0.21% (95% CI: 0.025%–0.75%) overall. Both the previous awareness of NPO status as risk factor and the low absolute number of events make meaningful comparison of this aspiration rate difficult.

Many clinically relevant issues are not addressed in this study. We are reluctant to report multiple post hoc analyses because of potentially misleading covariance patterns in seemingly independent variables. Univariate analyses that are not supported in logistic models provide examples of this phenomenon. Assignment of an ASA physical status score, which requires patient assessment, was associated with higher complication risk in univariate analysis but was actually a proxy for DS, becoming insignificant after stratification by sedation depth. Similarly, the risk reduction by GRA was more significant in patients who underwent bronchoscopy than in patients who underwent noninvasive radiologic procedures, but the logistic model deteriorated when

procedure and service were included because of inadequate sample size to analyze adequately all covariate patterns. We attribute any actual difference to awareness of the potential risks of DS with airway manipulation, possible documentation lapses, and possible differential rates of referral for anesthesiology services, rather than to the reduced utility of patient assessment before sedation in radiology. Likewise, the adequacy of sedation from the patient's perspective is only partly reflected by sedation scoring and overt sedation failure. Additional study of these issues is warranted.

Our intent in reporting the higher inherent risk of DS is to emphasize that adherence to practice guidelines can reduce the complication rate when DS is used. The adverse event rate was 0 (95% CI: 0%–11.6%) in patients who were deeply sedated according to all process guidelines. This criterion was met if a presedation risk assessment, ASA assignment, consent, plan, complete sedation score and vital sign recording, and postsedation assessment were documented. All of these elements are prompted on the sedation record; although documentation does not always reflect actual practice, this finding provides evidence of the validity of these elements in a structured sedation program.

CONCLUSION

We found direct evidence that elements of an AAP/ASA structured model for procedural sedation could be adopted by nonanesthesiologists with apparent risk reduction. Although the adverse event rate of DS was significantly higher than that of CS, patient evaluation with a GRA tool before formulating a sedation plan significantly reduced complications in patients who underwent DS. Regular assessment by quantitative sedation scoring reduced the risk of inadvertent DS. Knowledge of NPO status seemed to alter sedation plans, thereby yielding insufficient data to support or refute explicitly the safety advantage of AAP NPO guidelines. However, the event rate was minimized when all process guidelines were followed.

ACKNOWLEDGMENT

We wish to thank Mary O'Connor, MSN, MBA, for administrative support for the sedation program.

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Risk Reduction in Pediatric Procedural Sedation by Application of an American Academy of Pediatrics/American Society of Anesthesiologists Process Model

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Pediatrics 2002;109;236-243
DOI: 10.1542/peds.109.2.236