Complete Summary

GUIDELINE TITLE

Clinical policy: evidence-based approach to pharmacologic agents used in pediatric sedation and analgesia in the emergency department.

BIBLIOGRAPHIC SOURCE(S)

Mace SE, Barata IA, Cravero JP, Dalsey WC, Godwin SA, Kennedy RM, Malley KC, Moss RL, Sacchetti AD, Warden CR, Wears RL. Clinical policy: evidence-based approach to pharmacologic agents used in pediatric sedation and analgesia in the emergency department. Ann Emerg Med 2004 Oct;44(4):342-77. [83 references] PubMed

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GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY
DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Conditions necessitating the alleviation of anxiety, pain, or both

GUIDELINE CATEGORY

Management

CLINICAL SPECIALTY

Anesthesiology
Emergency Medicine
Pediatrics
Pharmacology

GUIDELINE OBJECTIVE(S)

To provide recommendations for the use of pharmacologic agents to achieve sedation and analgesia in pediatric patients undergoing procedures in the emergency department

TARGET POPULATION

Patients between the ages of 1 to 18 years who are in a hospital emergency department and have conditions necessitating the alleviation of anxiety, pain, or both

These guidelines exclude:

- Children younger than 1 year
- Patients receiving analgesia to treat pain without concomitant sedative use
- Intubated patients
- Inhalational anesthetics

INTERVENTIONS AND PRACTICES CONSIDERED

Management

1. Etomidate
2. Fentanyl/Midazolam
3. Ketamine
4. Methohexital
5. Pentobarbital
6. Propofol

MAJOR OUTCOMES CONSIDERED

- Efficacy and safety of six drugs used for procedural sedation and analgesia in pediatric patients in the ED
- Quality of care and patient satisfaction

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Multiple MEDLINE searches were done on each of the 6 drugs (etomidate, fentanyl/midazolam, ketamine, methohexital, pentobarbital, and propofol). The drug names were then combined with a search expression designed to identify adverse effects, apnea, vomiting/aspiration, laryngospasm, and hypotension. Finally, the results were limited to English-language studies published between 1966 and 2002 that examined human subjects aged 1 to 18 years. Variants on this search strategy, limiting results to clinical trials or to review articles, were also run.

Searches were done for pre-1966 articles by drug name and were limited to English-language studies; however, no studies from this search were selected for further scrutiny.

Several additional searches were done crossing specific drugs or drug combinations with the terms "conscious sedation" or "procedural sedation" or "procedures." A search of other relevant materials, such as textbooks and reference databases, identified 3 additional papers that were not indexed by drug name. A final set of searches was performed that did not use any specific drug names, but was limited to publication dates from 1966 to 2002, human subjects, subjects aged 1 to 18 years, and conscious sedation or pediatric sedation. A manual search was performed in the peer-reviewed emergency medicine literature for pertinent articles published in 2003.

References obtained on the searches were reviewed by panel members (title and abstract, where available) for relevance before inclusion in the pool of studies to be reviewed. Abstracts and articles were reviewed by subcommittee members, and pertinent articles were selected. These articles were evaluated, and those addressing the questions considered in this document were chosen for grading. Subcommittee members also supplied references from bibliographies of initially selected articles or from their own files.

NUMBER OF SOURCE DOCUMENTS

- **Etomidate**: After a review of 56 articles, the following source documents were included in final analysis: a total of 4 emergency department (ED)-based studies; 4 studies evaluating the presence of adrenal suppression; and 3 studies looking at myoclonus and/or pain with injection in patients receiving etomidate.
- **Fentanyl/Midazolam**: After a review of 28 articles, 14 articles were included in the final analysis.

- **Ketamine**: After a review of 29 articles, 19 articles were included in the final analysis.
- **Methohexital**: After a review of 50 articles, 6 articles were selected for inclusion in the final analysis.
- **Pentobarbital**: After a review of 14 articles, 11 studies were included for the final analysis.
- **Propofol**: After a review of 63 articles, 14 articles were selected for inclusion in the analysis.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Strength of evidence Class I - Interventional studies including clinical trials, observational studies including prospective cohort studies, aggregate studies including meta-analyses of randomized clinical trials only

Strength of evidence Class II - Observational studies including retrospective cohort studies, case-controlled studies, aggregate studies including other meta-analyses

Strength of evidence Class III - Descriptive cross-sectional studies, observational reports including case series and case reports, consensus studies including published panel consensus by acknowledged groups of experts

Strength of evidence Class I and II articles were then rated on elements the subcommittee members believed were most important in creating a quality work. Class I and II articles with significant flaws or design bias were downgraded on the basis of a set formula (refer to Appendix B in the original guideline document). Strength of evidence Class III articles were downgraded if they demonstrated significant flaws or bias. Articles downgraded below strength of evidence Class III were given an "X" rating and were not used in formulating recommendations in this policy.

Most of the studies included in this guideline lacked a standardized validated scoring system for evaluation of efficacy. In addition, the endpoints differed among the various studies. For many studies, efficacy was defined as the completion of the procedure without any measurement of the degree of sedation. When this occurred, the panel noted "efficacy was not address." When a success/failure rate was given, efficacy was graded as Class III. When there was a quantitative measure of sedation, efficacy was given a higher grade (Class I or II) depending on the overall assessment.

In considering the question of safety with respect to the administration of the various drugs included in this clinical policy, the panel recognized that there is not sufficient power in the peer-reviewed literature to document true "safety" for any of the agents involved in any setting, including the operating suite, because critical incidents of very low frequency would require patient cohorts of thousands

to be fully evaluated. Lacking this type of data, the panel considered all of the available information form studies that took place in an Emergency Department or analogous venue and graded safety on the basis of the available data.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Level A recommendations- Generally accepted principles for patient management that reflect a high degree of clinical certainty (i.e., based on strength of evidence Class I or overwhelming evidence from strength of evidence Class II studies that directly address all the issues)

Level B recommendations - Recommendations for patient management that may identify a particular strategy or range of management strategies that reflect moderate clinical certainty (i.e., based on strength of evidence Class II studies that directly address the issue, decision analysis that directly addresses the issue, or strong consensus of strength of evidence Class III studies)

Level C recommendations - Other strategies for patient management based on preliminary, inconclusive, or conflicting evidence, or in the absence of any published literature, based on panel consensus

There are certain circumstances in which the recommendations stemming from a body of evidence should not be rated as highly as the individual studies on which they are based. Factors such as heterogeneity of results, uncertainty about effect magnitude and consequences, strength of prior beliefs, and publication bias, among others, might lead to such a downgrading of recommendations.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Expert review comments were received on an earlier draft of this document from members of the American Academy of Pediatrics (AAP), the American Pediatric Surgical Association, the American Society of Anesthesiology (ASA), the Emergency Nurses Association, and the American College of Emergency Physicians. Their responses were used to further refine and enhance this policy.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions for the strength of evidence (Class I-III) and strength of recommendations (Level A-C) are repeated at the end of the "Major Recommendations" field.

Etomidate

Is etomidate effective for providing procedural sedation in children in the emergency department (ED)?

- ***Level A recommendations.*** None specified.
- ***Level B recommendations.*** None specified.
- ***Level C recommendations.*** Etomidate is an effective agent for procedural sedation in the pediatric patient population within the ED.

Is etomidate safe for providing procedural sedation in children in the ED?

- ***Level A recommendations.*** None specified.
- ***Level B recommendations.*** None specified.
- ***Level C recommendations.*** Etomidate is a safe agent for procedural sedation in the pediatric patient population within the ED.

Fentanyl/Midazolam

Are fentanyl and midazolam effective for providing procedural sedation in children in the ED?

- ***Level A recommendations.*** None specified.
- ***Level B recommendations.*** Intravenous use of fentanyl and midazolam is effective for pediatric sedation during painful procedures in the ED.
- ***Level C recommendations.*** None specified.

Is the use of fentanyl and midazolam safe for providing procedural sedation for painful procedures in children in the ED?

- ***Level A recommendations.*** None specified.

- ***Level B recommendations.*** The combination of fentanyl and midazolam appears to result in a greater risk of respiratory depression; therefore, the clinician should take particular care to monitor the patient for signs of respiratory depression and should have appropriate training and support to treat apnea.
- ***Level C recommendations.*** None specified.

Ketamine

Is ketamine effective for providing procedural sedation in children in the ED?

- ***Level A recommendations.*** Ketamine is effective either as a sole agent or in combination with a benzodiazepine for brief painful procedures in children.
- ***Level B recommendations.*** None specified.
- ***Level C recommendations.*** None specified.

Is ketamine safe for providing procedural sedation in children in the ED?

- ***Level A recommendations.*** Ketamine can be safely used for procedural sedation in children in the ED, but may require head positioning, supplemental oxygen, occasional bag-valve-mask ventilatory support, and measures to address laryngospasm.
- ***Level B recommendations.*** None specified.
- ***Level C recommendations.*** None specified.

Does the addition of midazolam as an adjunct to ketamine for procedural sedation for children in the ED reduce recovery agitation or vomiting?

- ***Level A recommendations.*** The addition of midazolam as an adjunct to ketamine for procedural sedation for children in the ED does not decrease the incidence of emergent reactions.
- ***Level B recommendations.*** The addition of midazolam as an adjunct to ketamine for procedural sedation for children decreases the incidence of emesis.
- ***Level C recommendations.*** None specified.

Methohexital

Is methohexital effective for providing procedural sedation in children in the ED?

- ***Level A recommendations.*** None specified.
- ***Level B recommendations.*** Methohexital administered by either the intravenous, intramuscular, or rectal routes can provide effective sedation for children undergoing painless diagnostic studies.
- ***Level C recommendations.*** None specified.

Is methohexital safe for providing procedural sedation in children in the ED?

- ***Level A recommendations.*** None specified.
- ***Level B recommendations.*** Methohexital can be safely used for procedural sedation but may require head positioning, supplemental oxygen, and occasional bag-valve-mask ventilatory support.
- ***Level C recommendations.*** None specified.

Pentobarbital

Is pentobarbital effective for providing procedural sedation in children in the ED?

- ***Level A recommendations.*** None specified.
- ***Level B recommendations.*** Pentobarbital alone is effective in producing cooperation for painless diagnostic procedures. Best sedation results are seen in children younger than 8 years.
- ***Level C recommendations.*** None specified.

Is pentobarbital safe for providing procedural sedation in children in the ED?

- ***Level A recommendations.*** None specified.
- ***Level B recommendations.*** Pentobarbital can be safely used for procedural sedation but may require head positioning, supplemental oxygen, and occasional bag-valve-mask ventilatory support.
- ***Level C recommendations.*** None specified.

Propofol

Is propofol effective for providing procedural sedation in children in the ED?

- ***Level A recommendations.*** None specified.
- ***Level B recommendations.*** Propofol combined with opiate agents is effective in producing cooperation for painful therapeutic or diagnostic studies.
- ***Level C recommendations.*** Propofol alone, without the concomitant use of opiate agents, is likely to be effective in producing sedation for painless diagnostic studies in ED patients.

Is propofol safe for providing procedural sedation in children in the ED?

- ***Level A recommendations.*** None specified.
- ***Level B recommendations.*** Propofol combined with opiate agents can be safely used for procedural sedation but may require head positioning, supplemental oxygen, and occasional bag-valve-mask ventilatory support.
- ***Level C recommendations.*** Propofol alone, without the concomitant use of opiate agents, can be safely used for procedural sedation but may require head positioning, supplemental oxygen, and occasional bag-valve-mask ventilatory support.

Definitions:

Strength of Evidence

Strength of evidence Class I - Interventional studies including clinical trials, observational studies including prospective cohort studies, aggregate studies including meta-analyses of randomized clinical trials only

Strength of evidence Class II - Observational studies including retrospective cohort studies, case-controlled studies, aggregate studies including other meta-analyses

Strength of evidence Class III - Descriptive cross-sectional studies, observational reports including case series and case reports, consensus studies including published panel consensus by acknowledged groups of experts

Strength of Recommendation

Level A recommendations - Generally accepted principles for patient management that reflect a high degree of clinical certainty (i.e., based on strength of evidence Class I or overwhelming evidence from strength of evidence Class II studies that directly address all the issues)

Level B recommendations - Recommendations for patient management that may identify a particular strategy or range of management strategies that reflect moderate clinical certainty (i.e., based on strength of evidence Class II studies that directly address the issue, decision analysis that directly addresses the issue, or strong consensus of strength of evidence Class III studies)

Level C recommendations - Other strategies for patient management based on preliminary, inconclusive, or conflicting evidence, or in the absence of any published literature, based on panel consensus

There are certain circumstances in which the recommendations stemming from a body of evidence should not be rated as highly as the individual studies on which they are based. Factors such as heterogeneity of results, uncertainty about effect magnitude and consequences, strength of prior beliefs, and publication bias, among others, might lead to such a downgrading of recommendations.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is identified and graded in the "Major Recommendations" field.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- This guideline is intended to help physicians provide safe and effective procedural sedation/analgesia in pediatric patients undergoing procedures in the Emergency Department.
- Proactively addressing pain and anxiety may improve quality of care and patient satisfaction by facilitating interventional procedures and minimizing patient suffering.

POTENTIAL HARMS

Because individuals vary in their response to medications, and sedation for analgesia is a continuum, the practitioner providing sedation and analgesia needs to be proficient in airway management and cardiovascular support.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This policy is not intended to be all encompassing and is a guideline. It represents evidence for answering important questions about critical diagnostic and management issues. Recommendations in this policy are not intended to represent the only diagnostic and management options that the emergency physician can consider. The authors clearly recognize the importance of the individual physician's judgment. Rather, this guideline defines for the physician those strategies for which medical literature exists to provide support for answers to the critical questions addressed in this policy.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Mace SE, Barata IA, Cravero JP, Dalsey WC, Godwin SA, Kennedy RM, Malley KC, Moss RL, Sacchetti AD, Warden CR, Wears RL. Clinical policy: evidence-based approach to pharmacologic agents used in pediatric sedation and analgesia in the emergency department. Ann Emerg Med 2004 Oct;44(4):342-77. [83 references] PubMed

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004 Oct

GUIDELINE DEVELOPER(S)

American College of Emergency Physicians - Medical Specialty Society

SOURCE(S) OF FUNDING

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GUIDELINE COMMITTEE

EMSC Grant Panel (Writing Committee) on Pharmacologic Agents Used in Pediatric Sedation and Analgesia in the Emergency Department

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

EMSC Grant Panel (Writing Committee) on Pharmacologic Agents Used in Pediatric Sedation and Analgesia in the Emergency Department Members: Sharon E.Mace, MD (Chair) (ACEP); Isabel A. Barata, MD (ACEP); Joseph P. Cravero, MD (American Society of Anesthesiologists); William C. Dalsey, MD (ACEP); Steven A. Godwin, MD (ACEP); Robert M. Kennedy, MD (American Academy of Pediatrics); Kelly C. Malley, CPNP, RN (Emergency Nurses Association); R. Lawrence Moss, MD (American Pediatric Surgical Association); Alfred D. Sacchetti, MD (ACEP); Craig R. Warden, MD, MPH (ACEP); Robert L. Wears, MD, MS, Methodologist (ACEP).

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

ENDORSER(S)

American Academy of Pediatrics - Medical Specialty Society
American Pediatric Surgical Association - Medical Specialty Society
Emergency Nurses Association - Medical Specialty Society

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American College of Emergency Physicians Web site.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on November 24, 2004. The information was verified by the guideline developer on January 14, 2005.

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