General

Guideline Title


Bibliographic Source(s)


Guideline Status

This is the current release of the guideline.


Regulatory Alert

FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- **December 14, 2016 – General anesthetic and sedation drugs:** The U.S. Food and Drug Administration (FDA) is warning that repeated or lengthy use of general anesthetic and sedation drugs during surgeries or procedures in children younger than 3 years or in pregnant women during their third trimester may affect the development of children’s brains. Consistent with animal studies, recent human studies suggest that a single, relatively short exposure to general anesthetic and sedation drugs in infants or toddlers is unlikely to have negative effects on behavior or learning. However, further research is needed to fully characterize how early life anesthetic exposure affects children’s brain development.

Recommendations

Major Recommendations

1. **Preoperative Patient Evaluation and Preparation**
   - Although the consultants and specialty society members agree that there are identifiable preoperative risk factors, at this time the Task
Force does not believe that there are identifiable preoperative patient characteristics that predispose patients to perioperative ischemic optic neuropathy (ION).

- Further, the Task Force believes that there is no evidence that an ophthalmic or neuro-ophthalmic evaluation would be useful in identifying patients at risk for perioperative visual loss.
- The Task Force believes that the risk of perioperative ION may be increased in patients who undergo prolonged procedures, have substantial blood loss, or both. (For the purposes of this Advisory, the Task Force considers such patients to have a higher risk for perioperative visual loss than patients who do not undergo prolonged procedures, have substantial blood loss, or both.)
- Consider informing patients in whom prolonged procedures, substantial blood loss, or both are anticipated that there is a small, unpredictable risk of perioperative visual loss.
- Because the frequency of visual loss after spine surgery of short duration is very low, the decision to inform patients who are not anticipated to be "high risk" for visual loss should be determined on a case-by-case basis.

II. Intraoperative Management

Blood Pressure Management

- Systemic blood pressure should be monitored continually in high-risk patients.
- The Task Force believes that the use of deliberate hypotensive techniques during spine surgery has not been shown to be associated with the development of perioperative visual loss.
  - Therefore, the use of deliberate hypotension for these patients should be determined on a case-by-case basis.

Management of Intraoperative Fluids

- Central venous pressure monitoring should be considered in high-risk patients.
- Colloids should be used along with crystalloids to maintain intravascular volume in patients who have substantial blood loss.

Management of Anemia

- Hemoglobin or hematocrit values should be monitored periodically during surgery in high-risk patients who experience substantial blood loss.
- The Task Force believes that there is no documented lower limit of hemoglobin concentration that has been associated with the development of perioperative visual loss.
  - Therefore, the Task Force believes a transfusion threshold that would eliminate the risk of perioperative visual loss related to anemia cannot be established at this time.

Use of Vasopressors

- The Task Force consensus is that there is insufficient evidence to provide guidance for the use of α-adrenergic agonists in high-risk patients during spine surgery.
  - Therefore, the decision to use α-adrenergic agonists should be made on a case-by-case basis.

Patient Positioning

- The Task Force believes that there is no pathophysiologic mechanism by which facial edema can cause perioperative ION.
- There is no evidence that ocular compression causes isolated perioperative anterior ION or posterior ION.
  - However, direct pressure on the eye should be avoided to prevent central retinal artery occlusion (CRAO).
- The high-risk patient should be positioned so that the head is level with or higher than the heart when possible.
- The high-risk patient's head should be maintained in a neutral forward position (e.g., without significant neck flexion, extension, lateral flexion, or rotation) when possible.

III. Staging of Surgical Procedures

- Although the use of staged spine surgery procedures in high-risk patients may entail additional costs and patient risks (e.g., infection, thromboembolism, or neurologic injury), it also may decrease these risks and the risk of perioperative visual loss in some patients.
  - Therefore, consideration should be given to the use of staged spine procedures in high-risk patients.

IV. Postoperative Management

- The consensus of the Task Force is that a high-risk patient's vision should be assessed when the patient becomes alert (e.g., in the recovery room, intensive care unit, or nursing floor).
- If there is concern regarding potential visual loss, an urgent ophthalmologic consultation should be obtained to determine its cause.
- Additional management may include optimizing hemoglobin or hematocrit values, hemodynamic status, and arterial oxygenation.
- To rule out intracranial causes of visual loss, consider magnetic resonance imaging.
- The Task Force believes that there is no role for antiplatelet agents, steroids, or intraocular pressure-lowering agents in the treatment of perioperative ION.
Clinical Algorithm(s)
None provided

Scope

Disease/Condition(s)
Perioperative visual loss associated with spine surgery, including:
- Posterior ischemic optic neuropathy
- Anterior ischemic optic neuropathy
- Central retinal artery occlusion

Guideline Category
Evaluation
Management
Prevention
Risk Assessment
Treatment

Clinical Specialty
Anesthesiology
Neurological Surgery
Neurology
Nursing
Ophthalmology
Orthopedic Surgery
Pediatrics

Intended Users
Advanced Practice Nurses
Allied Health Personnel
Nurses
Physician Assistants
Physicians

Guideline Objective(s)
To enhance awareness and reduce the frequency of perioperative visual loss

Target Population

Patients who are undergoing spine procedures while positioned prone and receiving general anesthesia

Note: This Advisory does not address the perioperative management of patients who receive regional anesthesia or sedation. This Advisory also does not include other causes of visual loss, such as cortical blindness. It does not include nonspine surgical procedures (e.g., cardiac surgery, radical neck dissection). In addition, this Advisory does not apply to young children because of the rarity of visual loss in children younger than 12 years of age undergoing spine surgery.

Interventions and Practices Considered

Preoperative Patient Evaluation and Preparation

1. Ophthalmic or neuro-ophthalmic evaluation (considered but not recommended)
2. Assessment of risk factors for vision loss and informing patients of risk factors

Intraoperative Management

1. Blood pressure management (deliberate hypotensive techniques)
2. Management of intraoperative fluids (e.g., use of colloids, crystalloids; central venous pressure monitoring)
3. Management of anemia (monitoring of hemoglobin, hematocrit)
4. Use of vasopressors
5. Patient positioning (maintenance of neutral forward position; head level with or higher than heart)
6. Use of staged spine surgical procedures

Postoperative Management

1. Assessing a high-risk patient's vision when the patient becomes alert
2. Urgent ophthalmologic consultation if concern regarding vision loss
3. Optimizing hemoglobin or hematocrit levels, hemodynamic status, and arterial oxygenation
4. Magnetic resonance imaging
5. Use of antithrombotics, steroids, intraocular pressure-lowering agents (considered but not recommended)

Major Outcomes Considered

- Risk for and occurrence of perioperative visual loss
- Effectiveness of procedures to identify risk for perioperative visual loss
- Effectiveness of procedures to prevent perioperative visual loss
- Effectiveness of procedures to assess the cause of perioperative visual loss
- Effectiveness of measures to restore lost vision

Methodology

Methods Used to Collect>Select the 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

State of the Literature

For this updated Advisory, a review of studies used in the development of the original Advisory was combined with a review of studies published subsequent to approval of the original Advisory. The updated literature review was based on evidence linkages, consisting of directional statements about relationships between specific perioperative management activities associated with a spine procedure during which general anesthesia is administered and permanent impairment or total loss of sight. The evidence linkage interventions are listed below. Unless otherwise specified, outcomes for the listed interventions refer to the occurrence of perioperative visual loss.

Preoperative Patient Evaluation and Preparation

- Ophthalmic or neuro-ophthalmic evaluation
- Vascular risk factors
- Preoperative anemia
- Prolonged procedures
- Substantial blood loss
- Prolonged procedures combined with substantial blood loss

Intraoperative Management

- Blood Pressure Management
  - Deliberate hypotension techniques in high-risk patients without preoperative chronic hypertension
  - Deliberate hypotension techniques in high-risk patients with well-controlled preoperative chronic hypertension
- Management of Intraoperative Fluids
  - Continual intravascular volume monitoring for high-risk patients
  - Central venous pressure monitoring for high-risk patient
  - Colloid and crystalloid balance for fluid resuscitation
  - Colloids versus crystalloids for fluid resuscitation and replacement
- Management of Anemia
  - Periodic monitoring of hemoglobin or hematocrit values
- Vasopressors
  - Prolonged use of high-dose-adrenergic agonists in high-risk patients

Patient Positioning

- Avoidance of direct pressure on the eye
- Positioning of head level with or higher than the heart in high-risk patients
- Placing head in a neutral forward position in high-risk patients
- Type of head positioning device
- Use of a horseshoe headrest
- Regular assessment and documentation of the eyes of prone-positioned patients
- Occurrence of perioperative facial edema in high-risk patients

Surgical Procedures

- Staging of procedures anticipated to be lengthy
- Staging of procedures anticipated to have substantial blood loss
- Staging of procedures anticipated to be lengthy with substantial blood loss

Postoperative Management

- Assessing a high-risk patient's vision when the patient becomes alert
- Magnetic resonance imaging
- Adjusting hemoglobin or hematocrit values upward in patients for whom ischemic optic neuropathy (ION) is suspected
- Increasing blood pressure in patients for whom ION is suspected
- Administering arterial oxygenation in patients for whom ION is suspected
- Administering antiplatelet agents, steroids, or intraocular pressure-lowering agents
For purposes of literature review, potentially relevant clinical studies were identified via electronic and manual searches of the literature. The updated electronic search covered a 10-yr period from 2002 through 2011. The manual search covered a 15-yr period of time from 1997 through 2011. The principal source of citations was PubMed, although citations were also obtained from the Cochrane database, direct internet searches, task force members, liaisons from other organizations, and from hand searches of references located in reviewed articles. More than 100 new citations that addressed topics related to the evidence linkages were identified. These articles were reviewed and combined with pre-2006 articles used in the original Advisory, resulting in a total of 51 articles that contained direct linkage-related evidence.

No evidence linkage contained sufficient literature with well-defined experimental designs and statistical information to conduct an analysis of aggregated studies (i.e., meta-analysis). A complete bibliography used to develop this updated Advisory, organized by section, is available as Supplemental Digital Content 2, http://links.lww.com/ALN/A786.

A study or report that appears in the published literature can be included as evidence in the development of an advisory if it meets four essential criteria. Failure to meet one or more of these criteria means that a study had features that did not make it suitable for analytic purposes. The four essential criteria are as follows: (1) the study must be related to one of the specified linkage statements; (2) the study must report a clinical finding or set of findings that can be tallied or quantified. This criterion eliminates reports that contain only opinion; (3) the study must report a clinical finding or set of findings that can be identified as the product of an original investigation or report. This criterion eliminates the repetitive reporting and counting of the same results, as may occur in review articles or follow-up studies that summarize previous findings, and (4) the study must use sound research methods and analytical approaches that provide a clear test or indication of the relationship between the intervention and outcome of interest. Because none of the studies in this updated Advisory met all four criteria, the published literature could not be used as a source of quantitative support.

Number of Source Documents

A total of 51 articles contained direct linkage-related evidence.

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Preparation of this update used the same methodological process as was used in the original Advisory to obtain new scientific evidence. Opinion-based evidence obtained from the original Advisory is reported in this update. The protocol for reporting each source of evidence is described below.

Scientific Evidence

Study findings from published scientific literature were aggregated and are reported in summary form by evidence category, as described below. All literature (e.g., randomized controlled trials, observational studies, case reports) relevant to each topic was considered when evaluating the findings. However, for reporting purposes in this document, only the highest level of evidence (i.e., level 1, 2, or 3 identified below) within each category (i.e., A, B, or C) is included in the summary.

Category A: Supportive Literature. Randomized controlled trials report statistically significant (P<0.01) differences between clinical interventions for a specified clinical outcome.

Level 1: The literature contains multiple randomized controlled trials, and the aggregated findings are supported by meta-analysis.

Level 2: The literature contains multiple randomized controlled trials, but there is an insufficient number of studies to conduct a viable meta-analysis.

Level 3: The literature contains a single randomized controlled trial.

Category B: Suggestive Literature. Information from observational studies permits inference of beneficial or harmful relationships among clinical interventions and clinical outcomes.
Level 1: The literature contains observational comparisons (e.g., cohort, case-control research designs) of clinical interventions or conditions and indicates statistically significant differences between clinical interventions for a specified clinical outcome.

Level 2: The literature contains noncomparative observational studies with associative (e.g., relative risk, correlation) or descriptive statistics.

Level 3: The literature contains case reports.

Category C: Equivocal Literature. The literature cannot determine whether there are beneficial or harmful relationships among clinical interventions and clinical outcomes.

Level 1: Meta-analysis did not find significant differences among groups or conditions.

Level 2: The number of studies is insufficient to conduct meta-analysis, and (1) randomized controlled trials have not found significant differences among groups or conditions or (2) randomized controlled trials report inconsistent findings.

Level 3: Observational studies report inconsistent findings or do not permit inference of beneficial or harmful relationships.

Category D: Insufficient Evidence from Literature. The lack of scientific evidence in the literature is described by the following terms.

Inadequate: The available literature cannot be used to assess relationships among clinical interventions and clinical outcomes. The literature either does not meet the criteria for content as defined in the “Focus” of the Advisory or does not permit a clear interpretation of findings due to methodological concerns (e.g., confounding in study design or implementation).

Silent: No identified studies address the specified relationships among interventions and outcomes.

Opinion-based Evidence

The original Advisory contained formal survey information collected from expert consultants and samples of active members of the Society for Neuroscience in Anesthesiology and Critical Care, North American Neuro-Ophthalmology Society, and the North American Spine Society. Additional information was obtained from open forum presentations and other invited and public sources. All opinion-based evidence relevant to each topic (e.g., survey data, open-forum testimony, Internet-based comments, letters, editorials) was considered in the development of the original Advisory. However, only the findings obtained from formal surveys are reported.

Survey responses from Task Force-appointed expert consultants and specialty society members obtained during development of the original Advisory are summarized in the text and reported in Appendix 2, Tables 1–4 in the original guideline document.

Responses were solicited from four response categories: agree, equivocal, disagree, and no opinion. Survey information is summarized in the text based on modal responses (e.g., a modal response of “agree” will be listed in the text as an agreement).

Methods Used to Analyze the Evidence

Other

Systematic Review

Description of the Methods Used to Analyze the Evidence

State of the Literature

Although evidence linkages are designed to assess causality, the reviewed studies did not provide a clear indication of causality. Therefore, the published literature could not be used as a source of quantitative support. However, many published studies were evaluated that provided the Task Force with important noncausal evidence. For example, descriptive literature (i.e., reports of frequency or incidence) is often useful in providing an indication of the scope of a problem, and case reports may be useful in identifying perioperative events that may be precursors to permanent visual impairment or total loss of sight. In conclusion, the current literature has not been helpful in determining the efficacy of specific perioperative management activities (i.e., associated with a spine procedure during which general anesthesia is administered) in reducing permanent impairment or total loss of sight. Until controlled studies are conducted, evidence from noncausal sources will need to be used, such as consensus-driven data.
and the opinion of practitioners and experts. It is recommended that future research on perioperative visual loss focus on the identification of patients at higher risk of perioperative visual loss in the context of prospective research designs when feasible.

In the original Advisory, interobserver agreement among Task Force members and two methodologists was established by interrater reliability testing. Agreement levels using a kappa (κ) statistic for two-rater agreement pairs were as follows: (1) type of study design, κ = 0.64–0.78; (2) type of analysis, κ = 0.74–0.87; (3) evidence linkage assignment, κ = 0.69–0.94; and (4) literature inclusion for database, κ = 0.77–1.00. Three-rater chance-corrected agreement values were: (1) study design, Sav = 0.69, Var (Sav) = 0.022; (2) type of analysis, Sav = 0.82, Var (Sav) = 0.017; (3) linkage assignment, Sav = 0.79, Var (Sav) = 0.007; and (4) literature database inclusion, Sav = 0.86 Var (Sav) = 0.030. These values represent moderate-to-high levels of agreement. For the updated Advisory, the same two methodologists involved in the original Advisory conducted the literature review.

Consensus-Based Evidence

For the original Advisory, consensus was obtained from multiple sources, including (1) survey opinion from consultants who were selected based on their knowledge or expertise regarding perioperative visual impairment or total loss of sight associated with a spine procedure during which general anesthesia is administered; (2) survey opinions from selected samples of active members of the Society for Neuroscience in Anesthesiology and Critical Care, the North American Neuro-Ophthalmology Society, and the North American Spine Society; (3) testimony from attendees of a publicly held open forum at a national anesthesia meeting; (4) Internet commentary, and (5) Task Force opinion and interpretation. The consultant survey rate of return was 60% (N = 18 of 30). Modal survey responses for consultants and specialty group members are presented in the text of the Advisory, and complete listings of survey responses are reported in Tables 1 to 4 in the original guideline document.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The original Advisory was developed by an American Society of Anesthesiologists (ASA)-appointed task force of 10 members, consisting of four anesthesiologists from various geographic areas of the United States, three neuro-ophthalmologists (one neurologist, two ophthalmologists), an orthopedic spine surgeon, a neurosurgeon, and two methodologists from the ASA Committee on Standards and Practice Parameters. Three physicians served as official liaisons from national organizations. They included a neuro-ophthalmologist (North American Neuro-Ophthalmology Society [NANOS]), an orthopedic surgeon (American Academy of Orthopaedic Surgeons), and a neurosurgeon (American Association of Neurological Surgeons).

The Task Force developed the original Advisory by means of a six-step process. First, it reached consensus on the criteria for evidence of effective perioperative interventions for the prevention of visual loss. Second, original published articles from peer-reviewed journals relevant to perioperative visual loss were evaluated. Third, consultants who had expertise or interest in perioperative visual loss and who practiced or worked in various settings (e.g., academic and private practice) were asked to: (1) participate in opinion surveys on the effectiveness of various perioperative management strategies, and (2) review and comment on a draft of the Advisory developed by the Task Force. Fourth, additional opinions were solicited from active members of the Society for Neuroscience in Anesthesiology and Critical Care, NANOS, and the North American Spine Society. Fifth, the Task Force held an open forum at a national anesthesia meeting to solicit input on the key concepts of this Advisory. Sixth, all available information was used to build consensus within the Task Force on the Advisory.

The draft document was made available for review on the ASA website, and input was invited via e-mail announcement to all ASA members. All submitted comments were considered by the Task Force in preparing the final draft.

In 2009, the ASA Committee on Standards and Practice Parameters requested that scientific evidence for this Advisory be updated. The update consists of an evaluation of literature published after completion of the original Advisory.

Rating Scheme for the Strength of the 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

Original Practice Advisory

Consultants who had expertise or interest in perioperative visual loss and who practiced or worked in various settings (e.g., academic and private practice) were asked to: (1) participate in opinion surveys on the effectiveness of various perioperative management strategies, and (2) review and comment on a draft of the Advisory developed by the Task Force. Additional opinions were solicited from active members of the Society for Neuroscience in Anesthesiology and Critical Care, North American Neuro-Ophthalmology Society, and the North American Spine Society. The Task Force held an open forum at a national anesthesia meeting to solicit input on the key concepts of this Advisory.

The draft document was made available for review on the American Society of Anesthesiology (ASA) website, and input was invited via e-mail announcement to all ASA members. All submitted comments were considered by the Task Force in preparing the final draft.

Updated Practice Advisory

The updated Practice Advisory was approved by the ASA House of Delegates on October 19, 2011.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The advisory statements contained in this document represent a consensus of the current spectrum of clinical opinion and literature-based findings.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Enhanced awareness and reduced frequency of perioperative visual loss

Potential Harms

The use of staged spine surgery procedures in high-risk patients may entail additional costs and patient risks (e.g., infection, thromboembolism, neurologic injury), but it also may decrease these risks and the risk of perioperative visual loss in some patients.

Qualifying Statements
Qualifying Statements

- Practice Advisories are systematically developed reports that are intended to assist decision-making in areas of patient care. Advisories provide a synthesis and analysis of expert opinion, clinical feasibility data, open forum commentary, and consensus surveys. Practice Advisories developed by the American Society of Anesthesiologists (ASA) are not intended as standards, guidelines, or absolute requirements, and their use cannot guarantee any specific outcome. They may be adopted, modified, or rejected according to clinical needs and constraints and are not intended to replace local institutional policies.
- Practice Advisories are not supported by scientific literature to the same degree as standards or guidelines because of the lack of sufficient numbers of adequately controlled studies.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Resources

For information about availability, see the Availability of Companion Documents and Patient Resources fields below.

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)


Adaptation

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