



Complete Summary

GUIDELINE TITLE

ASHP therapeutic guidelines on stress ulcer prophylaxis.

BIBLIOGRAPHIC SOURCE(S)

American Society of Health-System Pharmacists. ASHP therapeutic guidelines on stress ulcer prophylaxis. American Society of Health-System Pharmacists. Am J Health Syst Pharm 1999 Feb;56(4):347-79. [423 references]

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SCOPE

DISEASE/CONDITION(S)

- Stress ulcers (superficial lesions commonly, but not exclusively, involving the mucosal layer of the stomach that appear after major stressful events such as surgery and trauma)
- Stress-induced gastrointestinal bleeding associated with events such as trauma, surgery, and acute organ failure

GUIDELINE CATEGORY

Management
Treatment

CLINICAL SPECIALTY

Critical Care
Gastroenterology
Internal Medicine

INTENDED USERS

Pharmacists
Physicians

GUIDELINE OBJECTIVE(S)

To help health care professionals to identify appropriate candidates for stress ulcer prophylaxis and select cost-effective modalities for prophylaxis when prophylaxis is indicated

TARGET POPULATION

Adult and pediatric patients in intensive care units (ICU), including the following subgroups:

- General medical and surgical ICU adult patients, including trauma patients, patients with thermal injuries, patients undergoing neurosurgical procedures or with neurologic disorders, and transplantation patients
- Pediatric patients one month of age or older with thermal injuries

Adult and pediatric patients in non-ICU settings [Note: Stress ulcer prophylaxis is not recommended for patients (adult and pediatric) in non-ICU settings]

INTERVENTIONS AND PRACTICES CONSIDERED

Use of agents that are used for stress ulcer prophylaxis in the United States, whether or not the agents have FDA-approved labeling for this indication, including the following:

- Histamine H₂-receptor antagonists (e.g., cimetidine, famotidine, nizatidine, and ranitidine)
- Antacids
- Sucralfate
- Misoprostol
- Proton-pump inhibitors (e.g., lansoprazole, omeprazole)

MAJOR OUTCOMES CONSIDERED

Measures of the efficacy of prophylaxis:

- Episodes of clinically important gastrointestinal bleeding, defined as gastroduodenal bleeding associated with clinically important complications, such as hemodynamic compromise and the need for blood transfusions or surgery
- Mortality due to clinically significant bleeding
- Adverse effects of prophylactic agents, including the risk of nosocomial pneumonia

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

The guideline developer performed detailed and exhaustive literature searches of MEDLINE files dated from 1966 to 1997 and International Pharmaceutical Abstracts (IPA) files dated from 1970 to 1997. The searches of the two databases were compared to check for duplicates and were subsequently compared with the references listed in a recent meta-analysis by Cook et al. (Stress ulcer prophylaxis in critically ill patients: resolving discordant meta-analyses. *JAMA* 1996;275:308-14) for completeness.

Ten key articles pertinent to stress ulcer prophylaxis were identified and entered into MEDLINE to capture appropriate MeSH headings. Applicable MeSH headings were combined with relevant text words into five sets:

- Set A1 combined terms for the condition to be avoided in broad terms (e.g., peptic ulcer) by using the subheadings prevention and control and complications.
- Set A2 covered terms more specific to the condition being treated (e.g., peptic ulcer hemorrhage) by using the same subheadings.
- Set B included terms describing patient location (e.g., intensive care) or condition (e.g., critical illness).
- Set C covered terms related to the treatments to be considered (e.g., H₂-receptor antagonists) with the subheadings adverse effects and therapeutic use.
- Set D was the free-text term stress ulcer prophylaxis.

The sets were combined as [(A1 and B) or (A2 and C) or D]. The search was limited to reports on humans published in the English language. The search in IPA differed in that combining set A2 and C decreased the retrieval. The sets were combined in IPA as {[(A1 or A2) and B] or D}.

All relevant citations were printed and reviewed for pertinent articles, which were subsequently retrieved and copied. The reference lists of the retrieved articles were studied for investigations that may have been missed through the computerized search.

Periodic literature searches using the same method were conducted during the compilation of the guidelines. The reference lists of review articles were examined for potentially pertinent references. Unpublished abstracts (e.g., those presented at meetings) and abstracts in foreign languages were excluded.

Although all relevant articles were reviewed, they were not necessarily referenced in the final guideline. In particular, the guideline developer excluded isolated case reports or case series involving fewer than 25 patients unless they provided unique information that would substantially affect the recommendations. Similarly, pharmacokinetic and pharmacodynamic studies of medications were not included unless there was some applicability to stress ulcer prophylaxis.

NUMBER OF SOURCE DOCUMENTS

Not stated

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

I + Meta-analysis of randomized, controlled trials (RCTs) with homogeneity of results and a 95% confidence interval (CI) that lies entirely on one side of the numerical threshold for clinically important benefit

I Meta analysis of RCTs with homogeneity of results but with a 95% CI that includes the threshold for clinically important benefit

I - RCT in which the entire 95% CI lies on one side of the threshold for clinically important benefit

II + Meta-analysis of RCTs with heterogeneity of results and a 95% CI that lies entirely on one side of the threshold for clinically important benefit

II Meta-analysis of RCTs with heterogeneity of results and a 95% CI that includes the threshold for clinically important benefit

II - RCT in which the 95% CI includes the threshold for clinically important benefit

III + Nonrandomized concurrent cohort study in which the entire 95% CI lies on one side of the threshold for clinically important benefit

III Nonrandomized concurrent cohort study in which the 95% CI includes the threshold for clinically important benefit

IV+ Nonrandomized historic cohort study in which the entire 95% CI lies on one side of the threshold for clinically important benefit

IV Nonrandomized historic cohort study in which the 95% CI includes the threshold for clinically important benefit

V Case series suggesting clinically important benefit

METHODS USED TO ANALYZE THE EVIDENCE

Meta-Analysis of Randomized Controlled Trials
Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not applicable

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The American Society of Health-System Pharmacists (ASHP) Therapeutic Guidelines on Stress Ulcer Prophylaxis were prepared by the University of Arizona under contract to ASHP. The project was coordinated by two pharmacy specialists, one with expertise in critical care and the other with expertise in drug information, who consulted with two physicians and a nurse specialist from the Arizona Health Sciences Center. The project coordinators worked in conjunction with an independent multidisciplinary panel of seven clinical specialists (a surgeon, a nurse, and five pharmacists) representing adult or pediatric critical care. The panel was appointed by ASHP.

The methods of literature review of others (refer to the original guideline document) were modified slightly and expanded to include a category D that represents a panel consensus based on the clinical experience of the panel members and a paucity of quality supporting literature. Before reviewing the literature, the panel of experts agreed that a meta-analysis carried more weight than a randomized, controlled trial (RCT) in determining a recommendation unless at least two RCTs had similar results or one RCT was designed with a sample large enough to detect a difference of 50% or less in bleeding rates (considered the primary outcome) between the treatment and control groups with a power of >80% and an alpha of <0.05.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

The recommendations were categorized according to the strength of evidence:

Category A = levels of evidence I +, I, and I -

Category B = levels of evidence II +, II, and II -

Category C = levels of evidence III +, III, IV+, IV, and V

Category D = represents a panel consensus based on the clinical experience of the panel members and a paucity of quality supporting literature

COST ANALYSIS

A formal economic analysis from an institutional perspective was conducted as part of the guideline development process. The general steps of acceptable cost-effectiveness analysis were followed: identification of clinical choices, determination of costs and benefits, statement of time frame, determination of cost-effectiveness ratio, and performance of a sensitivity analysis. The authors encourage readers to make institution-specific decisions and to use the template

provided in the original guideline to construct their own institution-specific economic analysis.

The overall results are consistent with those of other published cost-effectiveness analyses that concluded that sucralfate is the most cost-effective agent for prophylaxis, with a saving of \$4913 for each episode of bleeding averted. The cost-effectiveness ratio for ranitidine was lower, with a cost saving of \$1766. Antacids were nearly cost neutral. The differences are particularly notable if the pH-altering medications are assumed to cause a higher rate of nosocomial pneumonia (0.8% for acid suppressants and 0 for sucralfate); this is true regardless of the route of administration for the H₂-receptor antagonists. If it is assumed that none of the medications cause adverse effects (including pneumonia) and that they are similar in efficacy, sucralfate and orally administered H₂-receptor antagonists would have similar costs.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guidelines underwent multidisciplinary field review in order to evaluate their validity, reliability, and utility in clinical practice. The final document was approved by the ASHP Commission on Therapeutics and the ASHP Board of Directors.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The recommendations were categorized according to the strength of evidence (See Rating Scheme for the Strength of Evidence in the Full Summary):

Category A = levels of evidence I +, I, and I -

Category B = levels of evidence II +, II, and II -

Category C = levels of evidence III +, III, IV+, IV, and V

Category D = represents a panel consensus based on the clinical experience of the panel members and a paucity of quality supporting literature

Indications for Prophylaxis

Adults: Risk factors for ICU patients have been delineated in trials comparing prophylaxis with no prophylaxis by using clinically important bleeding as an endpoint. Prophylaxis is recommended in patients with coagulopathy or patients requiring mechanical ventilation for more than 48 hours. (Strength of evidence = C) Prophylaxis is also recommended in patients with a history of GI ulceration or bleeding within one year before admission and in patients with at least two of the

following risk factors: sepsis, ICU stay of more than one week, occult bleeding lasting six days or more, and use of high-dose corticosteroids (>250 mg per day of hydrocortisone or the equivalent). (Strength of evidence = D)
Recommendations for specific prophylactic medications can be found in the Medications used for prophylaxis section.

Pediatrics: Although various risk factors have been associated with bleeding in pediatric patients, published RCTs have either not used clinically important bleeding as an outcome or had insufficient power to enable a definitive conclusion that prophylaxis provides protection. Risk factors that have been associated with clinically important bleeding include respiratory failure, coagulopathy, and a Pediatric Risk of Mortality Score of greater than or equal to 10. (Strength of evidence = C)

Indications in Special Populations

Adults: Prophylaxis is recommended for ICU patients with a Glasgow Coma Score of less than or equal to 10 (or the inability to obey simple commands) or thermal injuries to >35% of their BSA. (Strength of evidence = B) ICU patients with partial hepatectomy may also benefit from prophylaxis. (Strength of evidence = C) Prophylaxis may also be indicated in ICU patients with multiple trauma (e.g., Injury Severity Score of greater than or equal to 16), transplantation patients in the ICU perioperatively, ICU patients with hepatic failure, and ICU patients with spinal cord injuries. (Strength of evidence = D).

Pediatrics: For pediatric patients (one month of age or older) with thermal injuries, prophylaxis is recommended, but there is insufficient evidence to recommend prophylaxis based on any given percentage of BSA. (Strength of evidence = D) For other pediatric surgery or trauma patients, insufficient evidence is available to allow recommendations about prophylaxis to be made.

Agent of Choice

Adults: Given the conflicting results of several meta-analyses and a recent RCT (both with strengths of evidence = A), the choice among antacids, H₂-receptor antagonists, and sucralfate for use as prophylactic agents to prevent clinically important bleeding associated with stress in adult patients admitted to general medical and surgical ICUs should be made on an institution-specific basis. This choice should take into account concerns regarding administration (e.g., functioning GI tract), adverse-effect profile, and total costs. (Strength of evidence = D) Insufficient data on misoprostol or the proton-pump inhibitors are available to allow any recommendation about these agents to be made.

Pediatrics and Special Populations: The lack of comparative trials of these agents in pediatric and special populations (e.g., patients with burns, trauma patients, patients undergoing neurosurgical procedures or with neurologic disorders, and transplantation patients) precludes definitive recommendations as to the agent of choice in these situations. The choice of agent should be made on an institution-specific basis and should take into account concerns about administration (e.g., functioning GI tract), adverse-effect profile, and total costs.

Adverse Effects

Adults and Pediatrics: It is recommended that patients with a history of serious reactions to antacids, H₂-receptor antagonists, proton-pump inhibitors, or sucralfate avoid future use of the offending agent. There are no other absolute contraindications that would preclude the short-term use of any of these medications for stress ulcer prophylaxis. However, unless the benefits clearly exceed the risks, it is recommended that sucralfate and antacids be avoided in neonates (particularly premature neonates) because of the possibility of adverse effects (e.g., bezoar formation, accumulation of aluminum and magnesium). Also, it is recommended that aluminum-containing products such as sucralfate be avoided in children with renal failure because dosing information has not been well established. Whether acid-suppressing agents are associated with a higher rate of pneumonia than sucralfate is unresolved, although any difference between these medications would appear to be small. It is recommended that potential adverse effects be considered as part of the economic analysis when an agent is chosen. (Strength of evidence = D)

Monitoring

Adults and Pediatrics: It is recommended that all patients receiving medications for stress ulcer prophylaxis be monitored for bleeding and adverse drug effects. Paper techniques for measuring gastric pH have questionable validity and reliability, and there is no evidence that adjusting the dosage of pH-altering medications (antacids, H₂-receptor antagonists, proton-pump inhibitors) on the basis of these measurements influences patient morbidity or mortality. Despite the lack of supporting data, pH monitoring for antacids may be appropriate (goal pH of >3.5-4). Such monitoring may also be useful for H₂-receptor antagonists when standard dosage regimens might not be appropriate (e.g., in cases of renal dysfunction, for increased dosages due to perceived failure of therapy, in pediatric patients). (Strength of evidence = D)

Other Options

Adults and Pediatrics: It is premature to recommend the use of novel therapies (e.g., free-radical scavengers) in place of conventional agents for stress ulcer prophylaxis, although the limited number of studies have had promising results. (Strength of evidence = D)

Prevention of Recurrent Bleeding

Adults and Pediatrics: The lack of available trials prohibits definitive recommendations for preventing recurrent bleeding after an episode of stress-induced GI bleeding, although consideration could be given to increasing the dosage of the prophylactic agent, adding another medication, or switching to a different agent. (Strength of evidence = D)

Non-ICU Patients

Adults: Stress ulcer prophylaxis is not recommended for adult patients in non-ICU settings. (Strength of evidence = B) for general medical and surgical patients with fewer than two risk factors for clinically important bleeding; strength of evidence = D for patients with two or more risk factors)

Pediatrics: Stress ulcer prophylaxis is not recommended for pediatric general medical and surgical patients or special populations (e.g., transplantation) in non-ICU settings if fewer than two risk factors for bleeding are present. (Strength of evidence = D). Data are insufficient to allow recommendations to be made about the use of prophylaxis in pediatric patients with two or more risk factors. If prophylaxis is given, it should be discontinued once risk factors have resolved. (Strength of evidence = D)

Institution-Specific Guidelines

Adults: Given some of the unresolved issues regarding stress ulcer prophylaxis, it is recommended that institution-specific guidelines be developed on the basis of economic models such as the one included in this document. For institutions willing to accept the assumption that H₂-receptor antagonists and sucralfate have equal efficacy, the accompanying economic analysis found sucralfate to be the most cost-effective agent. Exceptions to the use of sucralfate include lack of oral or other gastric access for administration and, potentially, documented failure of prophylaxis with sucralfate. If ranitidine is assumed to be more effective than sucralfate without increasing the risk of pneumonia, ranitidine (and presumably other H₂-receptor antagonists) would be the drug of choice and would also result in a cost saving, although less than that achieved with sucralfate.

Pediatrics: There are also unresolved issues for pediatric patients. Institution-specific guidelines can be developed by using the economic models included in the original guideline, but the percentages and costs need to be tailored to this population on the basis of institution-specific data. There is supporting evidence in the literature that the risk of stress-induced bleeding is greater in pediatric patients with respiratory failure, coagulopathy, a Pediatric Risk of Mortality Score of greater than or equal to 10, and thermal injuries. Whether prophylaxis will reduce the risk of bleeding is yet to be proven in this population so there is no clear agent of choice at this time.

CLINICAL ALGORITHM(S)

An algorithm is provided for stress ulcer prophylaxis in adult patients.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence is ranked and identified for each recommendation (see Major Recommendations).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Identification of risk factors for adult and pediatric patients in intensive care units (ICU) for stress-related bleeding

- Appropriate use of prophylactic agents to prevent clinically important bleeding associated with stress in adult and pediatric patients admitted to general medical and surgical ICUs
- Prevention of stress-induced bleeding
- Appropriate monitoring of adult and pediatric patients for bleeding and adverse drug effects
- Prevention of recurrent bleeding
- Economic considerations: Inappropriate stress ulcer prophylaxis can be costly, but implementing guidelines may decrease the inappropriateness and the expense.

Subgroups Most Likely to Benefit:

Adult ICU Populations: Risk factors associated with bleeding for adult patients in ICUs include the presence of coagulopathy, mechanical ventilation for more than 48 hours, a history of GI ulceration or bleeding within one year before admission, sepsis, ICU stay of more than one week, occult bleeding lasting six days or more, and use of high-dose corticosteroids (>250 mg per day of hydrocortisone or the equivalent).

Pediatric ICU Populations: Risk factors associated with clinically important bleeding in pediatric patients include respiratory failure, coagulopathy, and a Pediatric Risk of Mortality Score of greater than or equal to 10.

POTENTIAL HARMS

Adverse effects of prophylactic agents: Most adverse effects attributable to antacids, H₂-receptor antagonists, and sucralfate are uncommon and occur in less than 1% of adult patients, particularly when given on a short-term basis (e.g., for less than two weeks).

Adverse effects of prophylactic agents may include esophageal and GI bezoar formation, accumulation of aluminum and magnesium, and nosocomial pneumonia. H₂-receptor antagonists and proton-pump inhibitors have the potential for drug-drug, drug-nutrient, and drug-test interactions through a variety of mechanisms.

Potential for inappropriate dosing: The lack of information related to pediatric dosing could result in either under-dosing with diminished efficacy or overdosing with increased adverse effects.

Subgroups Most Likely to be Harmed:

Adults: The frequency of adverse effects may increase if certain disease states are present, such as renal failure, when electrolyte accumulation secondary to antacid administration, or CNS disturbances secondary to administration of H₂-receptor antagonists. Sucralfate may cause substantial elevations in serum aluminum concentrations in adult patients with chronic renal insufficiency or in the elderly, although this does not appear to be a problem when the drug is used for less than two weeks in critically ill patients.

Children: Unless the benefits clearly exceed the risks, it is recommended that sucralfate and antacids be avoided in neonates (particularly premature neonates) because of the possibility of adverse effects (e.g., bezoar formation, accumulation of aluminum and magnesium). Also, it is recommended that aluminum-containing products such as sucralfate be avoided in children with renal failure because dosing information has not been well established. There is a possibility that pediatric patients may be more susceptible to some adverse effects (e.g., thrombocytopenia associated with cimetidine) than adults.

Pregnant or nursing women: Caution is advised for the use of prophylactic agents in pregnant or nursing women (refer to original guideline for further details).

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

1. The recommendations in this document may not be appropriate for use in all clinical situations. Decisions to follow these recommendations must be based on the professional judgment of the clinician and must take into account individual patient circumstances and available resources. These guidelines reflect current knowledge (at the time of publication) on the use of stress ulcer prophylaxis in critically ill patients. Given the dynamic nature of scientific information and technology, periodic review, updating, and revision are to be expected.
2. The guidelines include information for patients in all age groups for which there is literature. When age groups are not specifically cited, the discussion refers to the adult patient population. Few prospective, randomized studies in the pediatric population have been published, particularly with regard to clinically important bleeding. Where appropriate, the lack of age-specific data is specified. It is hoped that the guidelines will stimulate research in these areas.

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

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American Society of Health-System Pharmacists. ASHP therapeutic guidelines on stress ulcer prophylaxis. American Society of Health-System Pharmacists. Am J Health Syst Pharm 1999 Feb;56(4):347-79. [423 references]

ADAPTATION

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

DATE RELEASED

1999 Feb 15

GUIDELINE DEVELOPER(S)

American Society of Health-System Pharmacists - Professional Association

SOURCE(S) OF FUNDING

American Society of Health-System Pharmacists

GUIDELINE COMMITTEE

ASHP Commission on Therapeutics

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

The ASHP Therapeutic Guidelines on Stress Ulcer Prophylaxis were prepared by the University of Arizona under contract to ASHP. The project was coordinated by two pharmacy specialists, one with expertise in critical care and the other with expertise in drug information, who consulted with two physicians and a nurse specialist from the Arizona Health Sciences Center. The project coordinators worked in conjunction with an independent multidisciplinary panel of seven clinical specialists (a surgeon, a nurse, and five pharmacists) representing adult or pediatric critical care. The panel was appointed by ASHP.

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Panel members and contractors were required to disclose any possible conflicts of interest before their appointment.

GUIDELINE STATUS

This is the current release of the guideline.

These guidelines reflect current knowledge (at the time of publication) on the use of stress ulcer prophylaxis in critically ill patients. Given the dynamic nature of scientific information and technology, periodic review, updating, and revision are to be expected.

ASHP guidelines are reviewed and revised as needed, generally every three to five years.

GUIDELINE AVAILABILITY

Electronic copies: Available from the [American Society of Health-System Pharmacists \(ASHP\) Web site](#).

Print copies: Available from ASHP, 7272 Wisconsin Avenue, Bethesda, MD 20814.

AVAILABILITY OF COMPANION DOCUMENTS

None available

NGC STATUS

This summary was completed by ECRI on April 25, 1999. It was verified by the guideline developer on May 13, 1999.

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Date Modified: 11/15/2004

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