



Complete Summary

GUIDELINE TITLE

Practice management guidelines for prophylactic antibiotic use in penetrating abdominal trauma.

BIBLIOGRAPHIC SOURCE(S)

Practice management guidelines for prophylactic antibiotic use in penetrating abdominal trauma. Allentown (PA): Eastern Association for the Surgery of Trauma (EAST); 2000. 33 p. [45 references]

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Penetrating abdominal trauma

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Management
Prevention

CLINICAL SPECIALTY

Emergency Medicine
Internal Medicine
Surgery

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel

Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To present recommendations on the use of prophylactic antibiotics in penetrating abdominal trauma.

TARGET POPULATION

Patients with penetrating abdominal wounds

INTERVENTIONS AND PRACTICES CONSIDERED

1. Preoperative antibiotic prophylaxis
 - Penicillin and penicillin derivatives (penicillin G, mezlocillin, ampicillin, carbenicillin, ticarcillin, piperacillin, sulbactam)
 - Cephalosporins (cefotaxime, cefoxitin, cefazolin, cefamandole, cefotetan, ceftizoxime, cefoperazone, ceftriaxone, cephalothin)
 - Aminoglycosides (tobramycin, streptomycin, garamycin, gentamicin, kanamycin)
 - Chloramphenicol
 - Clindamycin
 - Erythromycin
 - Tetracycline, doxycycline
 - Metronidazole
 - Aztreonam, moxalactam
2. Combination versus single antibiotic therapy
3. Duration of therapy
4. Determination of optimal dosage in patients with hemorrhagic shock

MAJOR OUTCOMES CONSIDERED

Incidence of infection, including wound infection, intra-abdominal abscess, drain tract wound infection urinary tract infection, or bacteremia

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

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

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A MEDLINE search from 1976 to 1997 was performed using the following subject words: antibiotic prophylaxis; penetrating abdominal injuries; abdominal injuries-complications; peritonitis; wound infection-prevention and control; pharmacokinetics; trauma; and cost analysis. This search identified 55 English

language references. The bibliography of each article was reviewed for additional references, which were not identified in the original MEDLINE query. Letters to the editor, case reports, and review articles were deleted from further evaluation. Thirty-nine articles were identified for evidentiary review.

NUMBER OF SOURCE DOCUMENTS

39 source documents

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

Evidence Classification Scheme:

Class I: Prospective, Randomized, Double-Blinded Study

Class II: Prospective, Randomized, Non-Blinded Trial

Class III: Retrospective Analysis of Patient Series

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
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

The articles retrieved in the literature search were reviewed by five general surgeons and two pharmaceutical outcome researchers with interest in pharmacokinetics and health care economics. These individuals then collaborated to produce the guideline recommendations.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Level I: This recommendation is convincingly justifiable based on the available scientific information alone. It is usually based on Class I data, however, strong Class II evidence may form the basis for a level 1 recommendation, especially if

the issue does not lend itself to testing in a randomized format. Conversely, weak or contradictory Class I data may not be able to support a level 1 recommendation.

Level II: This recommendation is reasonably justifiable by available scientific evidence and strongly supported by expert critical care opinion. It is usually supported by Class II data or a preponderance of Class III evidence.

Level III: The recommendation is supported by available data but adequate scientific evidence is lacking. This recommendation is generally supported by Class III data. This type of recommendation is useful for educational purposes and in guiding future clinical research.

COST ANALYSIS

In the past 10 years, there have been four studies evaluating the cost of antibiotic therapy in trauma patients with penetrating abdominal wounds. One group of researchers compared moxalactam to gentamicin plus clindamycin in 50 patients. The strength of this study is the well-performed cost analysis which included hospital costs for drugs, laboratory tests, personnel time, and supplies. They observed no symptomatic, trauma-related infections in either treatment group. There were also no direct toxic effects from either agent. The mean drug cost for each regimen did not differ. However, when laboratory tests, personnel time, and supply cost were added to the drug cost, the mean cost of therapy per patient was 38% greater with gentamicin plus clindamycin compared to moxalactam. This study demonstrated the importance of considering all treatment costs when performing cost-effectiveness analysis of combination therapy.

In a similar study design, another group of researchers compared cefotaxime, ceftiofex, and gentamicin plus clindamycin. Twenty-five patients were entered into each treatment arm, and the septic complications were 8%, 4%, and 8%, respectively. The cost analysis included the same four categories (drug cost, laboratory tests, personnel time, and supply cost). The mean cost of therapy per patient was significantly less with the cefotaxime. Unfortunately, the authors did not specify the number of patients who had high-risk factors for the development of infection.

In a subsequent report using the same study design, these researchers used the same three antibiotic regimens for a 3- to 5- day course of prophylaxis in 129 patients. Only 17 patients had colon injuries. The infection rate for cefotaxime was 6.9%, ceftiofex was 2.3%, and gentamicin plus clindamycin was 6.9%. There was no statistical difference between groups. As in their previous study, the mean cost of therapy per patient was significantly lower for the cefotaxime group.

A third group of researchers compared aztreonam plus clindamycin with gentamicin plus clindamycin in 85 trauma victims with suspected penetrating intraabdominal injury. There were 34 colon injuries. They further analyzed the hospital cost by stratifying patients as infected versus non-infected. They concluded that, despite a lower infection rate in the aztreonam group, neither hospital nor pharmacy costs were significantly different compared with those in the gentamicin plus clindamycin group.

These cost analysis studies of antibiotic therapy would suggest that consideration of single agent therapy using a drug with aerobic and anaerobic coverage may be a cost-effective choice compared to the more traditional combination antibiotic regimen (gentamicin plus clindamycin).

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The draft document is submitted to all members of the panel for review and modification. Subsequently the guidelines are forwarded to the chairmen of the Eastern Association of Trauma ad hoc committee for guideline development. Final modifications are made and the document is forwarded back to the individual panel chairpersons.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Level I-III recommendations, and the class of data grading (I-III) are defined at the end of the "Major Recommendations" field.

The proven role of prophylactic antibiotics in penetrating abdominal trauma is to reduce the incidence of wound infections. However, numerous studies from the past two decades have compared one therapeutic agent against another without an appropriate placebo control. The reduced incidence of remote infections (urinary tract infection, thrombophlebitis, and pneumonia) found by these investigators without appropriate controls is of questionable benefit. The altered pharmacokinetics of drugs in patients undergoing resuscitation with crystalloid and/or blood products needs further investigation. Most authors agree that the increased volume of drug distribution with appropriate resuscitation suggests that standard dosing regimens are subtherapeutic. Prophylactic antibiotics are optimally administered prior to incision, the duration should be brief (≤ 24 hours) with no additional benefit associated with prolonged therapy. An adjusted dose for the hemodynamically unstable patients, may be of benefit.

A. Level I Recommendations

There is sufficient Class I and II data to recommend a single preoperative dose of prophylactic antibiotics with broad-spectrum aerobic and anaerobic coverage as a standard of care for trauma patients sustaining penetrating abdominal wounds. Absence of a hollow viscus injury requires no further administration.

B. Level II Recommendations

There is sufficient Class I and Class II data to recommend continuation of prophylactic antibiotics for only 24 hours in the presence of injury to any hollow viscus.

C. Level III Recommendations

There is insufficient clinical data to provide meaningful guidelines for reducing infectious risks in trauma patients with hemorrhagic shock. Vasoconstriction alters the normal distribution of antibiotics, resulting in reduced tissue penetration. To circumvent this problem, the administered dose may be increased two- or threefold and repeated after every 10th unit of blood product transfusion until there is no further blood loss. Once hemodynamic stability has been achieved, antibiotics with excellent activity against obligate and facultative anaerobic bacteria should be continued for periods that depend on the degree of wound contamination. Aminoglycosides have been demonstrated to exhibit sub-optimal activity in patients with serious injury, probably due to altered pharmacokinetics of drug distribution.

Definitions:

Recommendation Scheme:

Level I: The recommendation is convincingly justifiable based on the available scientific information alone. This recommendation is usually based on Class I data, however, strong Class II evidence may form the basis for a level 1 recommendation, especially if the issue does not lend itself to testing in a randomized format. Conversely, low quality or contradictory Class I data may not be able to support a level 1 recommendation.

Level II: The recommendation is reasonably justifiable by available scientific evidence and strongly supported by expert opinion. This recommendation is usually supported by Class II data or a preponderance of Class III evidence.

Level III: The recommendation is supported by available data but adequate scientific evidence is lacking. This recommendation is generally supported by Class III data. This type of recommendation is useful for educational purposes and in guiding future clinical research.

Classification Scheme:

Class I: Prospective, randomly assigned, double-blinded study

Class II: Prospective, randomly assigned, non-blinded trial

Class III: Retrospective series of patients or meta-analysis

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

Conclusions were based on evidence obtained from prospective, randomly assigned, double-blinded studies (Class I); prospective, randomly assigned, non-blinded studies (Class II); or retrospective series of patients or meta-analysis (Class III). The evidentiary tables included 12 class I articles, 24 Class II articles, and 3 Class III references.

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

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Reduced incidence of postoperative infectious complications in patients with penetrating abdominal injuries.

POTENTIAL HARMS

Not stated

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The guideline developers make the following recommendations regarding implementation:

Implementation involves extensive education and inservicing of nursing, resident, and attending staff members and has one important guiding principle: the guidelines must be available to the clinicians in real time while they are actually seeing the patient. The two most common ways to apply these are by using either a critical pathway or a clinical management protocol. A critical pathway is a calendar of expected events that has been found to be very useful within designated diagnosis-related groups. In trauma, where there are multiple diagnosis-related groups used for one patient, pathways have not been found to be easily applied with the exception of isolated injuries. Clinical management protocols, on the other hand, are annotated algorithms that answer the "if, then" decision making problems and have been found to be easily applied to problem-, process-, or disease-related topics. The clinical management protocol consists of an introduction, an annotated algorithm and a reference page. The algorithm is a series of "if, then" decision making processes. There is a defined entry point followed by a clinical judgment and/or assessment, followed by actions, which are then followed by outcomes and/or endpoints. The advantages of algorithms are that they convey the scope of the guideline, while at the same time organize the decision making process in a user-friendly fashion. The algorithms themselves are systems of classification and identification that should summarize the recommendations contained within a guideline. It is felt that in the trauma and critical care setting, Clinical management protocols may be more easily applied than critical pathways, however, either is acceptable provided that the formulated guidelines are followed. After appropriate inservicing, a pretest of the planned

guideline should be performed on a limited patient population in the clinical setting. This will serve to identify potential pitfalls. The pretest should include written documentation of experiences with the protocol, observation, and suggestions. Additionally, the guidelines will be forwarded to the chairpersons of the multi-institutional trials committees of the Eastern Association for the Surgery of Trauma, the Western Association for the Surgery of Trauma, and the American Association for the Surgery of Trauma. Appropriate guidelines can then be potentially selected for multi-institutional study. This process will facilitate the development of user friendly pathways or protocols as well as evaluation of the particular guidelines in an outcome based fashion.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness
Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

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

DATE RELEASED

2000

GUIDELINE DEVELOPER(S)

Eastern Association for the Surgery of Trauma - Professional Association

SOURCE(S) OF FUNDING

Eastern Association for the Surgery of Trauma (EAST)

GUIDELINE COMMITTEE

EAST Practice Management Guidelines Work Group

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Workgroup Members: Fred A. Luchette, MD; Anthony P. Borzotta, MD; Martin A. Croce, MD; Patricia A. O'Neill, MD; Dietmar H. Whittmann, MD; C. Daniel Mullins, PhD; Francis Palumbo, PhD, JD; Michael D. Pasquale, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

An update is not in progress at this time.

GUIDELINE AVAILABILITY

Electronic copies: Available (in Portable Document Format [PDF] format) from the [Eastern Association for the Surgery of Trauma \(EAST\) Web site](#).

Print copies: Available from the EAST Guidelines, c/o Fred A. Luchette, MD, Loyola University Medical Center, Department of Surgery Bldg. 110-3276, 2160 S. First Avenue, Maywood, IL 60153; Phone: (708) 327-2680; E-mail: fluchet@lumc.edu.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Practice Management Guidelines for Trauma: East Ad Hoc Committee on Guideline Development (Unabridged: Revised 1998 Mar 20). Available from the [Eastern Association for the Surgery of Trauma \(EAST\) Web site](#).

An excerpt is also available:

- Pasquale M, Fabian TC. Practice management guidelines for trauma from the Eastern Association for the Surgery of Trauma. J Trauma 1998 Jun;44(6):941-56; discussion 956-7.

Also available:

- Utilizing evidence based outcome measures to develop practice management guidelines: a primer. Allentown (PA): Eastern Association for the Surgery of Trauma; 2000. 18 p. Available from the [EAST Web site](#).

Print copies: Available from the EAST Guidelines, c/o Fred A. Luchette, MD, Loyola University Medical Center, Department of Surgery Bldg. 110-3276, 2160 S. First Avenue, Maywood, IL 60153; Phone: (708) 327-2680; E-mail: fluchet@lumc.edu.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on March 9, 2001. The information was verified by the guideline developer on May 4, 2001.

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