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The Spine Journal ■ (2013) ■

THE SPINE JOURNAL

Review Article

An evidence-based clinical guideline for antibiotic prophylaxis in spine surgery

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Received 21 March 2013; accepted 15 June 2013

Abstract

BACKGROUND CONTEXT: The North American Spine Society's (NASS) Evidence-Based Clinical Guideline on Antibiotic Prophylaxis in Spine Surgery provides evidence-based recommendations to address key clinical questions regarding the efficacy and the appropriate antibiotic prophylaxis protocol to prevent surgical site infections in patients undergoing spine surgery. The guideline is intended to address these questions based on the highest quality clinical literature available on this subject as of June 2011.

PURPOSE: Provide an evidence-based educational tool to assist spine surgeons in preventing surgical site infections.

STUDY DESIGN: Systematic review and evidence-based clinical guideline.

METHODS: This guideline is a product of the Antibiotic Prophylaxis in Spine Surgery Work Group of NASS Evidence-Based Guideline Development Committee. The work group consisted of neurosurgeons and orthopedic surgeons who specialize in spine surgery and are trained in the principles of evidence-based analysis. A literature search addressing each question and using a specific search protocol was performed on English language references found in MEDLINE (PubMed), ACP Journal Club, Cochrane Database of Systematic Reviews Database of Abstracts of Reviews of Effectiveness, Cochrane Central Register of Controlled Trials, EMBASE (Drugs and Pharmacology), and Web of Science to identify articles published since the search performed for the original guideline. The relevant literature was then independently rated using the NASS-adopted standardized levels of evidence. An evidentiary table was created for each of the questions. Final recommendations to answer each clinical question were developed via work group discussion, and grades were assigned to the recommendations using standardized grades of recommendation. In the absence of Levels I to IV evidence, work group consensus statements have been developed using a modified nominal group technique, and these statements are clearly identified as such in the guideline.

RESULTS: Sixteen clinical questions were formulated and addressed, and the answers are summarized in this article. The respective recommendations were graded by the strength of the supporting literature, which was stratified by levels of evidence.

CONCLUSIONS: The clinical guideline for antibiotic prophylaxis in spine surgery has been created using the techniques of evidence-based medicine and best available evidence to aid practitioners in the care of patients undergoing spine surgery. The entire guideline document, including the evidentiary tables, suggestions for future research, and all the references, is available

FDA device/drug status: Not applicable.

Author disclosures: ***WOS:*** Nothing to disclose. ***JLB:*** Support for travel to meetings for the study or other purposes: NASS ($<100). ***RF:*** Nothing to disclose. ***PGM:*** Support for travel to meetings for the study or other purposes: NASS ($200).

The disclosure key can be found on the Table of Contents and at www.TheSpineJournalOnline.com.

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http://dx.doi.org/10.1016/j.spinee.2013.06.030

electronically on the NASS Web site at http://www.spine.org/Pages/PracticePolicy/ClinicalCare/ClinicalGuidlines/Default.aspx and will remain updated on a timely schedule. © 2013 Elsevier Inc. All rights reserved.

Keywords: Antibiotic prophylaxis; Spine surgery; Surgical site infection

Introduction

In an attempt to improve and evaluate the knowledge base concerning the efficacy and appropriate protocol for antibiotic prophylaxis in spine surgery, the Antibiotic Prophylaxis in Spine Surgery Work Group of the North American Spine Society (NASS) Evidence-Based Clinical Guideline Development Committee updated the 2007 evidence-based clinical guideline on the topic. The Institute of Medicine has defined a clinical guideline as ''systematically developed statements to assist practitioner and patient decisions about health care for specific clinical situations'' [1].

The application of the principles of evidence-based medicine (EBM) to guideline development helps to create an explicit linkage between the final recommendations in the guideline and the evidence on which these recommendations are based [2]. When using the principles of EBM, the clinical literature is extensively searched to answer specific questions about a disease state or medical condition. The literature that is identified in the search is then rated as to its scientific merit using levels of evidence, determined by specific rule sets that apply to human and clinical investigations. The specific questions asked are then answered using studies of the highest possible levels of evidence that have been obtained from the searches. As a final step, the answers to the clinical questions are reformulated as recommendations that are assigned grades of strength related to the best clinical evidence available at the time of answering each question. The intent of the grade of recommendation is to indicate the strength of the evidence used by the work group in answering the question asked.

Methods

For this clinical guideline, the guideline development process was broken down into 11 steps:

Step 1: Guideline participants, trained in the principles of EBM, carefully reviewed the key questions and content of the 2007 guideline to determine if any questions needed to be updated or any new questions added.

Step 2: Work group members were assigned to a set of clinical questions.

Step 3: Work group members reviewed the original search parameters used in the 2007 guideline, and as necessary, updated the search terms and parameters to direct the literature search according to the NASS-instituted Literature Search Protocol.

Step 4: The literature search was then completed in by a medical research librarian according to the NASS Literature Search Protocol and stored in a cross-referencing database for future use or reference. The following electronic databases were searched for English language publications: MEDLINE (PubMed), ACP Journal Club, Cochrane Database of Systematic Reviews Database of Abstracts of Reviews of Effectiveness, Cochrane Central Register of Controlled Trials, EMBASE (Drugs and Pharmacology), and Web of Science.

Step 5: Work group members then reviewed all the abstracts from the literature search. The best research evidence available was identified and used to answer the targeted clinical questions. That is, if adequate Level I, Level II, or Level III studies were available to answer a specific question, the work group was not required to review Level IV or Level V evidence. Members independently developed evidentiary tables summarizing study conclusions, identifying strengths and weaknesses, and assigning levels of evidence in.

Step 6: To systematically control for bias, at least three work group members reviewed each article selected and independently assigned a level of evidence as per the NASS Levels of Evidence table.

Step 7: Work group members participated in Webcasts to update and formulate evidence-based recommendations and incorporate expert opinion when necessary. Expert physician opinion was incorporated only in which Levels I to IV evidence was insufficient and the work groups deemed a recommendation was warranted. For transparency in the incorporation of consensus, all consensus-based recommendations in this guideline are clearly stated as such. Voting on guideline recommendations was conducted using a modification of the nominal group technique in which each work group member independently and anonymously ranked a recommendation on a scale ranging from 1 (extremely inappropriate) to 9 (extremely appropriate) [3]. Consensus was obtained when at least 80% of work group members ranked the recommendation as 7, 8, or 9. When the 80% threshold was not attained, up to three rounds of discussion and voting were held to resolve disagreements. If the disagreements were not resolved after these rounds, no recommendation was adopted. When the recommendations were established, work group members developed guideline content, referencing the literature that supported the recommendations.

Step 8: The completed guideline was submitted to the NASS Evidence-Based Guideline Development Committee and the NASS Research Council for review and comment.

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Revisions to recommendations were considered only when substantiated by a preponderance of appropriate levels of evidence.

Step 9: Once evidence-based revisions were incorporated, the NASS Board of Directors reviewed and approved the submitted guideline.

Step 10: The NASS Board–approved guideline was submitted for inclusion in the National Guidelines Clearinghouse.

Step 11: The guideline recommendations will be reviewed every 3 years and the literature base updated by an EBM-trained multidisciplinary team with revisions to the recommendations developed in the same manner as in the original guideline development.

Results

Efficacy

Question 1: For patients undergoing spine surgery, does antibiotic prophylaxis result in decreased infection rates compared to patients who do not receive prophylaxis?

Preoperative prophylactic antibiotics are suggested to decrease infection rates in patients undergoing spine surgery [4–6].

Grade of Recommendation: B

For a typical uncomplicated lumbar laminotomy and discectomy, a single preoperative dose of antibiotics is suggested to decrease the risk of infection and/or discitis [6–8].

Grade of Recommendation: B

Question 2: For patients undergoing spine surgery without spinal implants, does antibiotic prophylaxis result in decreased infection rates as compared to patients who do not receive prophylaxis?

Prophylactic antibiotics are suggested to decrease the rate of spinal infections after uninstrumented lumbar spinal surgery [7–10].

Grade of Recommendation: B

Question 3: For patients undergoing spine surgery with spinal implants, does antibiotic prophylaxis result in decreased infection rates as compared to patients who do not receive prophylaxis?

Prophylactic antibiotics may be considered to decrease the rate of infections after instrumented spine fusion [11–13].

Grade of Recommendation: C

Question 4: What rate of surgical site infections can be expected with the use of antibiotic prophylaxis, considering both patients with and patients without medical comorbidities?

Despite appropriate prophylaxis, the rate of surgical site infections in spine surgery is 0.7% to 10% [6,11,12,14–22]. The expected rate for patients without comorbidities ranges from 0.7% to 4.3% and for patients with comorbidities ranges from 2.0% to 10%. Current best practice with antibiotic protocols has failed to eliminate (reach an infection rate of 0.0%) surgical site infections.

Work Group Consensus Statement

Despite appropriate prophylaxis, diabetes carries an increased infection rate compared with nondiabetic patients [14,18–20].

Level of Evidence: III

There is insufficient evidence to make a statement regarding the impact of obesity on the rate of surgical site infection in prophylaxed patients [14,17–20].

Level of Evidence: I (insufficient)

Protocol

Question 5: For patients receiving antibiotic prophylaxis prior to spine surgery, what are the recommended drugs, their dosages, and time of administration resulting in decreased postoperative infection rates?

Preoperative antibiotic prophylaxis is suggested to decrease infection rates in patients undergoing spine surgery. In typical uncomplicated spinal procedures, the superiority of one agent, dose, or route of administration over any other has not been clearly demonstrated. When determining the appropriate drug choice, the patient's risk factors, allergies, length and complexity of the procedure, and issues of antibiotic resistance should be considered [4,6–9,12,15,16,21,23–26].

Grade of Recommendation: B

In typical uncomplicated spinal procedures, a single dose of preoperative prophylactic antibiotics with intraoperative redosing as needed is suggested [12,16,24–26].

Grade of Recommendation: B

In patients with comorbidities or for those undergoing complicated spine surgery, alternative prophylactic regimens, including redosing, gram-negative coverage, or the addition of intrawound application of vancomycin or gentamicin, are suggested to decrease the incidence of surgical site infections compared with standard prophylaxis regimens.

Work Group Consensus Statement

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Question 6: For patients receiving antibiotic prophylaxis prior to spine surgery without spinal implants, what are the recommended drugs, their dosages and time of administration resulting in decreased postoperative infections rates?

Preoperative antibiotic prophylaxis is suggested to decrease infection rates in patients undergoing spine surgery without spinal implants. In these typical uncomplicated spinal procedures, the superiority of one agent, dose, or route of administration over any other has not been clearly demonstrated. When determining the appropriate drug choice, the patient's risk factors, allergies, length and complexity of the procedure, and issues of antibiotic resistance should be considered [6–9,21,23–26].

Grade of Recommendation: B

In typical uncomplicated open spine surgery without spinal implants, a single dose of preoperative prophylactic antibiotics with intraoperative redosing as needed is suggested [24–26].

Grade of Recommendation: B

Question 7: For patients receiving antibiotic prophylaxis prior to spine surgery with spinal implants, what are the recommended drugs, their dosages and time of administration resulting in decreased postoperative infections rates?

Preoperative antibiotic prophylaxis is suggested to decrease infection rates in patients undergoing spine surgery with spinal implants. In these complex spinal procedures, the superiority of one agent, dose, or route of administration over any other has not been clearly demonstrated. When determining the appropriate drug choice, the patient's risk factors, allergies, length and complexity of the procedure, and issues of antibiotic resistance should be considered [12,15].

Grade of Recommendation: B

In patients with risk factors for polymicrobial infection, appropriate broad-spectrum antibiotics are suggested to decrease the risk of infection when instrumented fusion is performed.

Work Group Consensus Statement

Question 8: What is a reasonable algorithmic approach for antibiotic selection for a given patient?

Simple uncomplicated spine surgery (without instrumentation or comorbidities): one single preoperative dose of antibiotic of choice with intraoperative redosing as needed.

Work Group Consensus Statement

Instrumented spine surgery, prolonged procedures, comorbidities (eg, diabetes, neuromuscular disease, cord injury, or general spine trauma): one single preoperative dose of antibiotic of choice plus consideration of additional gram-negative coverage and/or the application of intrawound vancomycin or gentamicin.

Work Group Consensus Statement

This algorithmic approach is supported by the studies included in the first seven questions addressed within this guideline.

Redosing

Question 9: For patients receiving antibiotic prophylaxis prior to spine surgery, what are the intraoperative redosing recommendations for the recommended drugs (including dosages and time of administration) resulting in decreased postoperative infection rates?

Intraoperative redosing within 3 to 4 hours may be considered to maintain therapeutic antibiotic levels throughout the procedure. The superiority of one drug has not been demonstrated in the literature. When determining the appropriate drug choice, the patient's risk factors, allergies, length and complexity of the procedure, and issues of antibiotic resistance should be considered.

Work Group Consensus Statement

Discontinuation

Question 10: For patients receiving antibiotic prophylaxis prior to spine surgery, does discontinuation of prophylaxis at 24 hours result in decreased or increased postoperative infection rates as compared to longer periods of administration?

For typical uncomplicated cases, a single dose of preoperative prophylactic antibiotics with intraoperative redosing as needed is suggested to decrease the risk of surgical site infection [12,16,24–26].

Grade of Recommendation: B

Prolonged postoperative regimens may be considered in complex situations (ie, trauma, cord injury, neuromuscular disease, diabetes, or other comorbidities). Comorbidities and complex situations reviewed in the literature include obesity, diabetes, neurologic deficits, incontinence, preoperative serum glucose level of >125 mg/dL or a postoperative serum glucose level of >200 mg/dL, trauma, prolonged multilevel instrumented surgery, and other comorbidities [17,18].

Grade of Recommendation: C

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Wound drains

Question 11: For patients receiving antibiotic prophylaxis prior to spine surgery and who receive placement of wound drains at wound closure, does discontinuation of prophylaxis at 24 hours result in decreased or increased postoperative infection rates as compared to discontinuation of antibiotics at time of drain removal?

A comprehensive review of the literature did not yield evidence to address the question related to the effect on postoperative infection rates of the duration of prophylaxis in the presence of a wound drain.

There is insufficient evidence to make a recommendation for or against the early discontinuation of antibiotic prophylaxis in patients with wound drains [16].

Grade of Recommendation: I (insufficient evidence)

The use of drains is not recommended as a means to reduce infection rates after single-level surgical procedures [27].

Grade of Recommendation: I (insufficient evidence)

Body habitus

Question 12: For patients receiving antibiotic prophylaxis prior to spine surgery, should the recommended protocol differ based upon body habitus (eg, body mass index)?

Obese patients are at higher risk for postoperative infection, when given a standardized dose of antibiotic prophylaxis. In spite of this conclusion, there is insufficient evidence to make a recommendation for or against recommending a different protocol for patients based on body habitus [13,14,17,18].

Grade of Recommendation: I (insufficient evidence)

Comorbidities

Question 13: For patients receiving antibiotic prophylaxis prior to spine surgery, do comorbidities (other than obesity) such as diabetes, smoking, nutritional depletion and immunodeficiencies alter the recommendations for antibiotic prophylaxis?

In patients with comorbidities or for those undergoing complicated spine surgery, alternative prophylactic regimens are suggested to decrease the incidence of surgical site infections compared with standard prophylaxis regimens.

Work Group Consensus Statement

There is insufficient evidence to make a recommendation for or against the specific alternative regimens that are efficacious. However, promising alternative regimens that have been studied include redosing, gram-negative coverage, and the addition of intrawound application of vancomycin or gentamicin [7,8,12,15,18,26,28].

Grade of Recommendation: I (insufficient evidence)

Question 14: For patients with a history of MRSA infection, does prophylaxis with vancomycin reduce infections with MRSA compared to other antimicrobial agents?

Although no literature was available to address this specific question about patients with a history of Methicillin-resistant Staphylococcus aureus (MRSA), the search did identify studies that addressed prophylaxis to reduce infections with MRSA.

There is insufficient evidence to make a recommendation for or against the prophylactic use of vancomycin compared with other antimicrobial agents to reduce infections with MRSA [15,29].

Grade of Recommendation: I (insufficient evidence)

Complications

Question 15: What are the incidence and severity of complications/adverse events resulting from the use of prophylactic antibiotics?

Reported isolated complications related to prophylactic antibiotics include flushing, hypotension, rashes, intramembranous colitis and, most seriously, Stevens-Johnson Syndrome [7,15,16,21–23,25,30].

Work Group Consensus Statement

Question 16: What strategies can be implemented to minimize complications/adverse events resulting from the use of prophylactic antibiotics in spine surgery?

In typical uncomplicated spinal procedures, a single dose of preoperative prophylactic antibiotics with intraoperative redosing as needed is suggested to reduce the risk of complications/adverse events.

Reported isolated complications/adverse events related to prophylactic antibiotics are discussed in the previous section and include flushing, hypotension, rashes, intramembranous colitis and, most seriously, Stevens-Johnson Syndrome [7,15,16,21–23,25,30].

Work Group Consensus Statement

Discussion

This evidence-based clinical guideline for antibiotic prophylaxis in spine surgery has several functions. It is an educational tool for both clinicians and patients, and as such, this particular guideline is intended to assist spine surgeons in preventing surgical site infections. This guideline also serves to focus and rate the clinical data on this topic. An

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evidence-based guideline such as this allows a physician access to the best and most current evidence and reduces the burden of ''keeping up with the literature'' that spans innumerable journals from a broad spectrum of disciplines. In addition, this evidence-based clinical guideline has the potential to improve the appropriateness and effectiveness of patient care by basing decisions on the best evidence available.

Finally, the creation of this guideline serves to identify knowledge gaps in the clinical literature on antibiotic prophylaxis protocols for spine surgery. High-quality clinical guidelines ideally identify and suggest future research topics to improve guideline development and thus patient care, as detailed in the current guideline. The complete clinical guideline summarized in this article along with extensive descriptive narratives on each topic outlining the evidence and the work group rationale for the answers to each question can be found on the NASS Web site at http://www.spine.org/Pages/PracticePolicy/ClinicalCare/ClinicalGuidlines/Default.aspx. In addition, more extensive descriptions are provided for the guideline development process used at NASS, along with all the references used in this guideline and suggestions for future research studies on preventing surgical site infections and antibiotic prophylaxis use in spine surgery.

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