Complete Summary

GUIDELINE TITLE

Assessment: use of epidural steroid injections to treat radicular lumbosacral pain. Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology.

BIBLIOGRAPHIC SOURCE(S)

Armon C, Argoff CE, Samuels J, Backonja MM, Therapeutics and Technology Assessment Subcommittee of the American. Assessment: use of epidural steroid injections to treat radicular lumbosacral pain: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Neurology 2007 Mar 6;68(10):723-9. [27 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Radicular lumbosacral pain (sciatica)

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Treatment

CLINICAL SPECIALTY

Neurology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To provide recommendations on the utility of epidural steroid injections to treat lumbosacral pain

TARGET POPULATION

Individuals with radicular lumbosacral pain

INTERVENTIONS AND PRACTICES CONSIDERED

Epidural steroid injections to treat radicular lumbosacral pain

MAJOR OUTCOMES CONSIDERED

- Improvement in radicular lumbosacral pain
- Functionality
- Need for surgery
- Long-term pain relief
- Safety

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

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

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Efficacy

Medline searches were conducted in April 2003 and February 2005 using combinations of the terms "epidural injections" or "epidural steroids," "double-blind," "placebo-controlled," and "radiculopathy." A search of the Cochrane database of systematic reviews found no review on the use of epidural steroid injections to treat radicular pain. The following inclusion criteria were used: 1) clear case definition; 2) clear measure of outcome (pain relief) using a standardized measure; 3) use of a control group (placebo or active); 4) randomization; 5) at least double-blind study design, so that neither patient nor assessor of measure of outcome would know the treatment arm; or triple-blind, if the physician injecting the treatment also did not know what treatment was administered; 6) prospective study design; 7) adequate statistical analysis.

The references of articles identified primarily and within select review articles were scanned for additional articles meeting the inclusion criteria: none were found. Articles identified by reviewers of earlier versions of the manuscript were considered also. The highest level of evidence was used to make the conclusions and recommendations for this parameter. Since articles on epidural steroid treatment of radicular cervical pain did not meet these criteria, epidural steroids to treat radicular lumbosacral pain alone will be considered.

Safety

A separate Medline search using the key words "epidural steroid" and "complications" was performed to identify reported complications with the procedure. Results from selected articles and from the efficacy studies selected for inclusion are summarized briefly.

NUMBER OF SOURCE DOCUMENTS

The search yielded 37 articles, 4 of which met the predetermined inclusion criteria.

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

Classification of Evidence for Therapeutic Intervention

Class I: Prospective, randomized, controlled clinical trial with masked outcome assessment, in a representative population. The following are required: a) primary outcome(s) clearly defined; b) exclusion/inclusion criteria clearly defined; c) adequate accounting for dropouts and crossovers with numbers sufficiently low to have minimal potential for bias; and d) relevant baseline characteristics are presented and substantially equivalent among treatment groups or there is appropriate statistical adjustment for differences.

Class II: Prospective matched group cohort study in a representative population with masked outcome assessment that meets a–d above OR a randomized controlled trial (RCT) in a representative population that lacks one criteria a–d.

Class III: All other controlled trials (including well-defined natural history controls or patients serving as own controls) in a representative population, where outcome is independently assessed, or independently derived by objective outcome measurement.*

Class IV: Evidence from uncontrolled studies, case series, case reports, or expert opinion.

* Objective outcome measurement: an outcome measure that is unlikely to be affected by an observer's (patient, treating physician, investigator) expectation or bias (e.g., blood tests, administrative outcome data).

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The search of electronic databases yielded 37 articles, 4 of which met the predetermined inclusion criteria. These are summarized in an evidence table (Table 2 in the original guideline document). Full review of a fifth article resulted in its exclusion since outcome measures were unclear, times for the reported outcomes were uncertain, and results of statistical analysis for the outcomes of interest were unavailable. The two articles identified as of the highest quality in the Institute of Clinical Systems Improvement review were summarized also in Table 2 in the original guideline document. Some of the studies combined steroids with a local anesthetic, using the local anesthetic as a control or normal saline as the control, while others compared steroids to normal saline.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Classification of Recommendations

A = Established as effective, ineffective, or harmful for the given condition in the specified population. (Level A rating requires at least two consistent Class I studies.)

B = Probably effective, ineffective, or harmful for the given condition in the specified population. (Level B rating requires at least one Class I study or at least two consistent Class II studies.)

C = Possibly effective, ineffective, or harmful for the given condition in the specified population. (Level C rating requires at least one Class II study or two consistent Class III studies.)

U = Data inadequate or conflicting; given current knowledge, treatment is unproven.

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

Draft guidelines were reviewed for accuracy, quality, and thoroughness by the American Academy of Neurology (AAN) members, topic experts, and pertinent physician organizations.

Final guidelines were approved by the Therapeutics and Technology Assessment Subcommittee on July 28, 2006; by the Practice Committee on November 11, 2006; and by the AAN Board of Directors on December 7, 2006.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions of the strength of the recommendations (A, B, C, U) and classification of the evidence (Class I through Class IV) are provided at the end of the "Major Recommendations" field.

1. Epidural steroid injections may result in some improvement in radicular lumbosacral pain when determined between 2 and 6 weeks following the injection, compared to control treatment (**Level C, Class I–III evidence**). The average magnitude of effect is small, and the generalizability of the observation is limited by the small number of studies, limited to highly selected patient populations, the few techniques and doses studied, and variable comparison treatments.
2. In general, epidural steroid injections for radicular lumbosacral pain have shown no impact on average impairment of function, on need for surgery, or on long-term pain relief beyond 3 months. Their routine use for these indications is not recommended (**Level B, Class I–III evidence**).
3. Data on use of epidural steroid injections to treat cervical radicular pain are inadequate to make any recommendation (**Level U**).

Definitions

Classification of Evidence for Therapeutic Intervention

Class I: Prospective, randomized, controlled clinical trial with masked outcome assessment, in a representative population. The following are required: a) primary outcome(s) clearly defined; b) exclusion/inclusion criteria clearly defined; c) adequate accounting for dropouts and crossovers with numbers sufficiently low to have minimal potential for bias; and d) relevant baseline characteristics are presented and substantially equivalent among treatment groups or there is appropriate statistical adjustment for differences.

Class II: Prospective matched group cohort study in a representative population with masked outcome assessment that meets a–d above OR a RCT in a representative population that lacks one criteria a–d.

Class III: All other controlled trials (including well-defined natural history controls or patients serving as own controls) in a representative population, where outcome is independently assessed, or independently derived by objective outcome measurement.*

Class IV: Evidence from uncontrolled studies, case series, case reports, or expert opinion.

* Objective outcome measurement: an outcome measure that is unlikely to be affected by an observer's (patient, treating physician, investigator) expectation or bias (e.g., blood tests, administrative outcome data).

Classification of Recommendations

A = Established as effective, ineffective, or harmful for the given condition in the specified population. (Level A rating requires at least two consistent Class I studies.)

B = Probably effective, ineffective, or harmful for the given condition in the specified population. (Level B rating requires at least one Class I study or at least two consistent Class II studies.)

C = Possibly effective, ineffective, or harmful for the given condition in the specified population. (Level C rating requires at least one Class II study or two consistent Class III studies.)

U = Data inadequate or conflicting; given current knowledge, treatment is unproven.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

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

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of epidural steroid injections to treat lumbosacral pain

POTENTIAL HARMS

The most common complication is a transient headache whether or not associated with identifiable dural puncture. More serious complications, summarized in a 1996 review, were several cases of aseptic meningitis, arachnoiditis, and conus medullaris syndrome, typically after multiple subarachnoid injections. Two cases of epidural abscess, one case of bacterial meningitis, and one case of aseptic meningitis were also listed (subarachnoid drug placement could not be ruled out in the meningitis cases). A retroperitoneal hematoma was reported in one patient on anticoagulant therapy who received a fluoroscopically guided transforaminal injection of steroids. Transient complications have been encountered also during fluoroscopically guided caudal epidural injections, including insomnia, transient non-positional headaches, increased back pain, facial flushing, vasovagal reactions, nausea, and increased leg pain. No major neurologic complications (spinal hematomas) were encountered in a series of 1,035 individuals who received epidural steroid injections while on antiplatelet therapy. Minor complications (blood during needle placement) were encountered in 5.2%, and transient worsening of symptoms or emergence of new neurologic symptoms for more than 24 hours after the injection occurred in 4% of patients with median duration of 3 days and range 1 to 20 days. Additional qualitative safety data reporting serious complications were rare. An additional potential risk of radiographically guided transforaminal injections is radiation exposure; however, the radiation exposure of the spinal interventionalist was well within safety limits if proper techniques were followed

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This statement is provided as an educational service of the American Academy of Neurology (AAN). It is based on an assessment of current scientific and clinical information. It is not intended to include all possible proper methods of care for a particular neurologic problem or all legitimate criteria for choosing to use a specific procedure. Neither is it intended to exclude any reasonable alternative methodologies. The AAN recognizes that specific patient care decisions are the prerogative of the patient and the physician caring for the patient, based on all of the circumstances involved.

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
Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

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

DATE RELEASED

2007 Mar 6

GUIDELINE DEVELOPER(S)

American Academy of Neurology - Medical Specialty Society

SOURCE(S) OF FUNDING

American Academy of Neurology (AAN)

GUIDELINE COMMITTEE

Therapeutics and Technology Assessment Subcommittee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The American Academy of Neurology (AAN) is committed to producing independent, critical and truthful clinical practice guidelines (CPGs). Significant efforts are made to minimize the potential for conflicts of interest to influence the recommendations of this CPG. To the extent possible, the AAN keeps separate those who have a financial stake in the success or failure of the products appraised in the CPGs and the developers of the guidelines. Conflict of interest forms were obtained from all authors and reviewed by an oversight committee prior to project initiation. AAN limits the participation of authors with substantial conflicts of interest. The AAN forbids commercial participation in, or funding of, guideline projects. Drafts of the guideline have been reviewed by at least three AAN committees, a network of neurologists, *Neurology* peer reviewers, and representatives from related fields. The AAN Guideline Author Conflict of Interest Policy can be viewed at www.aan.com. With regards to this specific report, all authors have stated that they have nothing to disclose. One of the authors performs epidural steroid injections.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: A list of American Academy of Neurology (AAN) guidelines, along with a link to a Portable Document Format (PDF) file for this guideline, is available at the AAN Web site.

Print copies: Available from the AAN Member Services Center, (800) 879-1960, or from AAN, 1080 Montreal Avenue, St. Paul, MN 55116.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- AAN guideline development process [online]. St. Paul (MN): American Academy of Neurology. Available from the American Academy of Neurology Web site.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI Institute on May 14, 2007.

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