Cervical Epidural Steroid Injections

Review & Recommendation Statement
March 2011

NASS
NORTH AMERICAN SPINE SOCIETY

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Cervical Epidural Steroid Injections
Review & Recommendation Statement
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Review and Recommendation Statement: Evidence Work Group
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The evidentiary tables developed by the authors are available in a separate document titled *Cervical Epidural Steroid Injections: Review and Recommendation Statement Evidentiary Tables*, and can be accessed at [http://www.spine.org/Pages/PracticePolicy/ClinicalCare/ScientificPolicyComments/Default.aspx](http://www.spine.org/Pages/PracticePolicy/ClinicalCare/ScientificPolicyComments/Default.aspx).
Introduction

Cervical epidural steroid injection (CESI) is used to treat cervical radicular pain and cervical radiculopathy which have an estimated annual incidence of 83.2/100,000 persons. The condition can be associated with significant pain and disability. Patients who are candidates for CESI typically have not responded to some form(s) of medical treatment, and have often had recent cross sectional imaging studies that correlate with their clinical findings.

This statement is intended to present the current state of the evidence about the use of CESI to treat cervical radiculopathy/radiculitis and provide evidence-based recommendations regarding their use in treating cervical radicular pain.

This document supercedes any other existing NASS documents, with the exception of current clinical guidelines.

Topic Questions

The work group identified and has attempted to address the following three key clinical questions in this review and recommendation statement:

1. Does the use of CESIs improve the outcomes of cervical radiculopathy/radiculitis?
2. Are there prognostic indicators that predict which patients are likely to benefit from cervical epidural steroid injections?
3. What are the risks associated with administration of cervical epidural steroid injections?

Revision Date

This statement will be reviewed no more than two years following publication.

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Author Disclosures

John E. Easa, MD  Nothing to disclose.
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Zoher Ghogawala, MD, FACS  Research Support (Staff/Materials): Wallace Foundation (Level F, Private Research Foundation, Paid directly to institution/employer); Grants: National Institute of Health (Level C, UL1 RR024146 CTSA Grant (Yale University), Paid directly to institution/employer).
Daniel J. Mazanec, MD  Nothing to disclose.
William O. Shaffer, MD  Consulting: DePuy Spine (Financial, Level B consulting, iliolumbar module 12/09 and none since, Paid directly to institution/employer); Trips/Travel: Synthes (Financial, ProDisc C course. I paid for travel, lodging, meals and car rental. Training at no cost); Relationships Outside the One Year Requirement: DePuy Spine (Upcoming Committee Meeting [Cervical Epidural Work Group], 01/2007, Royalties, Level C).
Jeffrey T. Summers, MD  Board of Directors: First Choice Insurance Group (Financial, Pain Management representative to the Board. There is a Level A remuneration for each Board meeting attended during weekdays. In the past year, I have been paid Level A), International Spine Intervention Society (ISIS) (Nonfinancial, I am on the ISIS Board of Directors. I also serve as Treasurer. Travel expenses (airfare, hotel and parking) are provided when traveling to a Board meeting (official business only)).
David R. O'Brien, MD  Speaking and/or teaching arrangements: NASS (Both, Level A to Level B/year stipend for teaching coding course and travel-hotel expenses for teaching various courses and/or committee work); Trips/Travel: International Spinal Intervention Society (Both, Reimbursement for travel-hotel for attending Board of Directors meetings, approximately Level B), 2010 Spine and Technology Spine Summit (Financial, Speaker 2010 Spine and Technology Spine Summit; travel and Stipend Level B).
Christopher J. Standaert, MD  Consulting: Washington State Health Care Authority Health Technology Clinical Committee (Financial, Level B per meeting (one day), 4-5 meetings per year).

Range Key:
Level A. $100 to $1,000
Level B. $1,001 to $10,000
Level C. $10,001 to $25,000
Level D. $25,001 to $50,000
Level E. $50,001 to $100,000
Level F. $100,001 to $500,000
Level G. $500,001 to $1M
Level H. $1,000,001 to $2.5M
Level I. Greater than $2.5M

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Methodology

■ Step 1: Identification of Work Groups
A multidisciplinary team was identified and assigned to a work group. Because NASS is comprised of surgical, medical and interventional specialists, it is imperative to the development process that a cross-section of the NASS membership is represented on each group. This also helps to ensure that the potential for inadvertent biases in evaluating the literature and formulating recommendations is minimized. Work group participants were required to have participated in evidence analysis training or have passed a proficiency test in assigning levels of evidence (Appendix A).

■ Step 2: Identification of Clinical Questions
Work group participants were asked to submit a list of clinical questions that the statement should address. The lists were compiled into a master list, which was then circulated to each work group member with a request that they independently rank the questions in order of importance for consideration. The most highly ranked questions, as determined by the participants, served to focus the statement. The final list of questions was also reviewed and approved by the Review and Recommendation Statement Oversight Committee.

■ Step 3: Identification of Search Terms and Parameters
One of the most crucial elements of evidence analysis to support development of recommendations for appropriate clinical care is the comprehensive literature search. Thorough assessment of the literature is the basis for the review of existing evidence and the formulation of evidence-based recommendations. In order to ensure a thorough literature search, NASS has instituted a Literature Search Protocol (Appendix B) which has been followed to identify literature for evaluation in review and recommendation statement development. In keeping with the Literature Search Protocol, work group members have identified appropriate search terms and parameters to direct the literature search.

Specific search strategies, including search terms, parameters and databases searched, are documented in the appendices (Appendix C).

■ Step 4: Completion of the Literature Search
Once each work group identified search terms/parameters, the literature search was implemented by a medical/research librarian, consistent with the Literature Search Protocol.

■ Step 5: Review of Search Results/Identification of Literature to Review
Work group members reviewed all abstracts yielded from the literature search and identified the literature they would review in order to address the clinical questions, in accordance with the Literature Search Protocol. Members identified the best research evidence available to answer the targeted clinical questions. That is, if Level I, II and or III literature is available to answer specific questions, the work group was not required to review Level IV or V studies.
Step 6: Evidence Analysis
Members independently developed evidentiary tables summarizing study conclusions, identifying strengths and weaknesses and assigning levels of evidence.

As a final step in the evidence analysis process, members identified and documented gaps in the evidence to educate readers about where evidence is lacking and help guide further needed research.

Step 7: Formulation of Evidence-Based Recommendations and Incorporation of Expert Consensus
Work groups held Web casts to discuss the evidence-based answers to the clinical questions, the grades of recommendations and the incorporation of expert consensus. Expert consensus has been incorporated only where Level I-IV evidence is insufficient and the work group has deemed that a recommendation is warranted. Transparency in the incorporation of consensus is crucial, and all consensus-based recommendations made in this statement very clearly indicate that Level I-IV evidence is insufficient to support a recommendation and that the recommendation is based only on expert consensus.

Consensus Development Process

Voting on 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"). 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 disagreements were not resolved after these rounds, no recommendation was adopted.

After the recommendations were established, statement content was developed, addressing the literature which supports the recommendations.

NOTE: Steps 1-7 apply to the development of the evidentiary review portion of the Review and Recommendation Statement, not the Practice and Coverage Considerations.

Step 8: Submission of the Draft Review and Recommendation Statement for Review/Comment
The statement was submitted to the Review and Recommendation Statement Oversight Committee and the full NASS membership for review and comment. Edits and revisions to recommendations and any other content were considered for incorporation only when substantiated by a preponderance of appropriate level evidence, where evidence exists.

Step 9: Submission for Board Approval
Once any revisions were incorporated by the work group and Oversight Committee, the statement was submitted for NASS Board review and approval. Edits and revisions to recommendations and any other content were considered for incorporation only when substantiated by a preponderance of appropriate level evidence, where evidence exists.

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Step 10: Dissemination
Once Board-approved, the statement was shared with the NASS membership and made available via posting on the NASS Web site.

Step 11: Review and Revision Process
The recommendations will be reviewed at least every two years by a multidisciplinary team and the statement will be revised as appropriate based on a thorough review and assessment of relevant literature published since the development of this version of the review and recommendation statement.
Review and Recommendations

Does the use of cervical epidural steroid injections improve the outcomes of cervical radiculopathy/radiculitis?

Both transforaminal and interlaminar epidural steroid injections may be considered to provide short and long-term relief of cervical radiculitis.

Grade of Recommendation: C

There is fairly consistent Level III and IV evidence that transforaminal and interlaminar cervical epidural steroid injections (CESI) provide relief in 60-70% of patient with cervical radiculitis. This treatment seems to be fairly well maintained over time as demonstrated in studies with greater than one year follow-up. There were no studies available comparing the efficacy of interlaminar injections to transforaminal injections. In the absence of direct comparison studies, there is no recommendation for the route of administration. The studies reviewed used computed tomography (CT), fluoroscopy and even "blind" techniques (no imaging) in the performance of the injections. Therefore, in the absence of comparative studies, a specific imaging preference could not be incorporated into the recommendation. Similarly, the studies reviewed did not consistently report similar pre-injection therapeutic interventions, nor direct comparisons with non-invasive therapies. As a result, the work group did not feel the evidence supported stratifying a particular intervention over another, as would be implied by recommending epidural injections only after the failure of other treatments.

Anderberg et al1 described a prospective comparative study assessing the short-term benefit of a single transforaminal epidural steroid injection (TFESI) in patients with cervical radiculopathy. The authors reported finding no difference in outcome at three week follow-up between the 20 patients who received the TFESI and the 20 who received saline with local anesthetic. The authors concluded that there appears to be no benefit to adding steroid to a tranforaminal epidural injection and suggested that further studies are required. In critique, no validated outcome measures were utilized in this small study, and there are questions about the randomization process. In addition, there was no true control group since those designated as controls received an injection with anesthetic. Due to these limitations, this potential Level II study provides Level III therapeutic evidence that the use of Depo-Medrol with local anesthetic does not provide more pain relief at three weeks than local anesthetic plus saline.

Bush et al2 reported a prospective case series designed to monitor the clinical outcome of patients when using serial periradicular/epidural corticosteroid injection techniques in the management of cervical radiculopathy. All 68 patients included in the study received a cervical plexus block as the first injection. If not effective, patients were then treated with TFESI. If the TFESI did not provide pain relief, then patients received an interlaminar injection. Only 16% of the patients included in the study received CESI. At mean 39 month follow-up, no patients had surgery and 76% (48/63) reported no arm pain. The authors concluded that patients with cervical radiculopathy make an adequate recovery with periradicular or cervical epidural injections. This study provides...
Level IV therapeutic evidence that epidural steroid injections may provide long-term relief and avoidance of surgery.

Castagnera et al\(^3\) described a prospective case series assessing the short, mid and long-term effectiveness of a single interlaminar CESI (ICESI) performed with or without morphine in patients with chronic cervical radicular pain (CRP) of noncompressive and nonmalignant origin whose indications did not require surgery. Of the 24 patients included in the study, 14 received steroid and lidocaine and 10 received steroid and morphine. Three months following the ICESI, complete and excellent results were observed to the same degree in both groups: 71.4% and 70% in the lidocaine and morphine group, respectively. Improvement did not vary three months after the ICESI. Three months after the ICESI, 54% (13/24) of the patients stopped taking analgesics and 55% (11/20) stopped taking anxiolytics. The authors concluded that in patients suffering from CRP unrelated to a compressive or malignant lesion and not needing surgery, a single ICESI could be helpful when medical treatment fails. This study provides Level IV therapeutic evidence that ICESI may provide long-term relief for patients with cervical radicular pain who failed 12 months of medical treatment and did not require surgery.

Cyteval et al\(^4\) reported a retrospective case series evaluating the feasibility, tolerance and efficacy of cervical transforaminal periganglionic steroid infiltration under CT control in patients with a radiculopathy resistant to conventional medical treatment. Excellent results [at least 75% reduction in visual analog scale score (VAS)] were reported in 37% (11/30) and good results (at least 50% reduction) were achieved in 23% (7/30) of patients. The mean VAS decreased from 6.5 to 3.3 at two weeks and was maintained at six months. The authors concluded that intraradicular injection produced substantial and sustained relief of symptoms. This study provides Level IV therapeutic evidence that transforaminal epidural steroid injections under CT guidance in patients with cervical radiculopathy may provide significant reduction in pain in about 60% of patients.

Dreyfuss et al\(^5\) performed a prospective case series comparing the efficacy of nonparticulate (dexamethasone) and particulate (triamcinolone) steroids in ESI of patients with cervical radiculopathy. Both groups demonstrated clinically and statistically significant improvement in VAS at four weeks. The mean VAS decreased from 4.8 to 2.9 with 7% complete relief in the dexamethasone group and from 4.9 to 1.7 with 27% complete relief in the triamcinolone group. The authors concluded that there was no statistically significant difference in outcome between particulate and nonparticulate injections. This study provides Level IV therapeutic evidence that TFESI may provide significant short-term symptomatic relief of radicular pain in about 25-33% of patients.

Fish et al\(^6\) described a retrospective case series assessing whether magnetic resonance imaging (MRI) findings predict outcome of CESI. Of the 32 patients included in the study, patients with neuroforaminal stenosis, disc herniation and root compression did not show statistically significant improvement in outcomes compared with central canal stenosis. All patients in all groups showed superior improvement to patients with negative MRI findings. The authors concluded that patients with central canal stenosis have significantly better outcome than patients without. This study provides Level IV therapeutic evidence that CESI may be more effective in patients with central canal stenosis and radicular pain.

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Kim et al\textsuperscript{7} conducted a prospective case series to evaluate the feasibility and outcome of cervical transforaminal epidural steroid injection guided by multislice CT. In the 19 patients included in the study, significant reductions in VAS scores were maintained at 16 weeks. The authors concluded that CT guided CESI is safe and effective. This study provides Level IV therapeutic evidence that CT guided ESI may be effective in providing short-term relief of cervical radicular pain.

Kolstad et al\textsuperscript{8} reported a prospective case series to assess if fluoroscopically-guided transforaminal epidural steroid injections applied to a cohort of patients waiting for cervical disc surgery reduce the pain of cervical radiculopathy and hence reduce the need for surgical intervention. Statistical improvement in pain relief was seen at six weeks, and five of the 21 patients included in the study improved enough to cancel surgery. The authors concluded that preoperative CESI reduces the number of persons needing surgery. This study provides Level IV therapeutic evidence that CESI may be effective in treating cervical radiculopathy.

Kumar et al\textsuperscript{9} described a retrospective case series evaluating the efficacy of selective nerve root blocks (SNRB) in treating cervical radiculopathy using a two needle technique. In the 33 patients receiving fluoroscopically-guided TFESI using a two needle technique, VAS scores significantly improved from 7.4 to 2.2 at six weeks and 2.0 at 12 months. Also highly significant was improvement in the Neck Disability Index (NDI) with improvements from 66.9 to 31.7 at six weeks and 31.1 at 12 month follow-up. The authors concluded that SNRB is an effective treatment for cervical radiculopathy without significant motor deficit. This study provides Level IV therapeutic evidence that the use of cervical transforaminal epidural steroid injections may provide a reduction in pain for up to 12 months.

Kwon et al\textsuperscript{10} performed a retrospective case series to verify the effectiveness of fluoroscopically-guided interlaminar CESI in patients with neck and radicular pain, and identify prognostic factors for response to injection. Of the 33 patients with radiculopathy only, 79% (26/33) showed improvement in VAS scores at two weeks, while 67% (20/30) of the patients with neck pain and radiculopathy improved. The authors concluded that interlaminar CESI is a safe and effective short-term treatment for neck pain and radiculopathy. This study provides Level IV therapeutic evidence that interlaminar ESI may be an effective short-term treatment for cervical radiculopathy.

Lee et al\textsuperscript{11} reported a retrospective case series including 159 patients comparing the effectiveness of particulate (triamcinolone) and nonparticulate (dexamethasone) fluoroscopically-guided TFCESI in cervical radiculopathy. At one month follow-up 76.1% of all patients showed short-term improvement (80.4% triamcinolone; 69.4% dexamethasone). The authors concluded that cervical epidural steroid injections are effective in short-term management of cervical radiculopathy. This study provides Level IV therapeutic evidence that TFESI may provide short-term benefit to patients with cervical radiculopathy.

Lin et al\textsuperscript{12} described a retrospective case series examining the efficacy of fluoroscopically-guided TFESI treatment of symptomatic cervical disc herniations. At mean follow-up of 13 months, of the 70 patients included in the study, 63% (44/70) avoided surgery. The authors concluded that approximately two thirds of patients with cervical disc herniation and radiculopathy obtain short-term relief with CESI. This study provides Level IV therapeutic evidence that TFESI may provide short-term benefit to patients with cervical radiculopathy.

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Pasqualucci et al\textsuperscript{13} conducted a prospective case series comparing the outcomes of intermittent CESI and continuous epidural infusion in 141 patients with cervical radiculopathy. Patients with chronic (>180 days) symptoms had a significantly greater response to continuous infusion compared to intermittent CESI. Patients experiencing symptoms of less than 180 days duration showed no significant difference in symptoms between the two treatments. This study provides Level IV therapeutic evidence that both continuous and intermittent interlaminar CESI may provide improvement in the pain associated with chronic (>180 day symptom duration) radiculopathy, though continuous infusion may provide better benefit at six months.

Razzaq et al\textsuperscript{14} reported a retrospective case series assessing the long-term efficacy of fluoroscopically-guided CESI. Of the 19 patients included in the study, 43% (9/19) achieved significant or moderate relief of pain at six month follow-up. The authors concluded that CESI may benefit some patients with cervical radiculopathy. This study provides Level IV therapeutic evidence that 43% of patients with symptoms of radiculopathy have moderate relief of symptoms for at least six months following TFESI.

Rowlingson et al\textsuperscript{15} described a retrospective case series attempting to define clinical indications for and effectiveness of CESI. At 8-9 month follow-up, 24% (6/25) of the patients had an excellent response and 40% (10/25) reported a good response. The authors concluded that CESI produces a good-excellent result in 64% of patients and should be in the armamentarium of pain anesthesiologists. This study provides Level IV therapeutic evidence that nonfluoroscopically-guided interlaminar CESI produces a good-excellent result in 64% of patients at 8-9 months follow-up.

Slipman et al\textsuperscript{16} performed a retrospective case series evaluating the outcomes of SNRB in cervical spondylitic radicular pain. An average of 2.2 injections were administered to 20 patients, with outcomes assessed at a mean 21.2 month follow-up. There was a significant improvement in VAS pain scores and reported medication use with no change in work status. The authors concluded that SNRB is clinically effective in managing cervical spondylitic radicular pain. This study provides Level IV therapeutic evidence that TFESI may be effective in reducing pain and medication use in patients with cervical radiculopathy.

Stav et al\textsuperscript{17} conducted a prospective comparative study assessing pain relief and range of motion in 50 patients with cervical radiculopathy treated with CESI versus tender/trigger point injection (TPI). At one week, 76% of patients in the CESI group had good/very good improvement compared with 35.5% in the TPI group. At one year, 68% of patients in CESI group had good/very good improvement compared with 11.8% in the TPI group. The authors concluded that CESI is an effective short and long-term treatment for cervical radiculopathy. In critique, patients in this small study were not consecutively assigned to treatment groups and there was a 32% (8/25) drop out rate in the TPI group. Due to these limitations, this potential Level II study provides Level III therapeutic evidence that interlaminar CESI may provide good/very good short (one week) and long-term (>one year) improvement in symptoms of radiculopathy.

Vallee et al\textsuperscript{18} reported a prospective case series evaluating the efficacy of periradicular corticosteroid injection in patients with chronic cervical radiculopathy. Of the 32 patients included in the study, 62% reported good-

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excellent (>50% improvement from baseline pain score) relief of radicular symptoms at 14 days, with 53% reporting good–excellent results at six months. Patients with shorter duration of pain demonstrated higher response rates. The authors concluded that in patients with chronic cervical radiculopathy, periradicular injection produces durable improvement in greater than 50% of patients. This study provides Level IV therapeutic evidence that TFESI may provide short-term (14 days) relief in 63% and longer term (six month) relief in 53% of patients with symptoms of cervical radicular pain.

**Future Directions for Research**

A prospective comparative study of interlaminar epidural steroid injections as compared with transforaminal epidural steroid injections and a “control” group or physical therapy group, would provide at least Level II evidence with regard to which route of administration is most effective, if there is a difference, in treating cervical radiculitis.

**REFERENCES**


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ADDITIONAL REFERENCES REVIEWED


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Are there prognostic indicators that predict which patients are likely to benefit from cervical epidural steroid injections?

Cervical epidural steroid injection (CESI) is suggested for treating radicular pain in the majority of cases when either disc herniation, foraminal stenosis or central canal stenosis pathology is identified.

Grade of Recommendation:  B

Several studies were reviewed to address the question of whether there are certain prognostic indicators that can assist in predicting which patients are most likely to benefit from CESIs.

Cyteval et al\(^1\) described a retrospective comparative study evaluating the feasibility, tolerance and efficacy of cervical transforaminal periganglionic steroid infiltration under CT control in patients with radiculopathy resistant to conventional medical treatment. Of the 30 patients followed for six months, 16 were diagnosed with foraminal degenerative stenosis and 14 with foraminal obstruction due to disc herniation. The study found that CESI was effective in 60% of patients, with the type of pathology (disc herniation versus foraminal stenosis) not predictive of results. The authors concluded that cervical foraminal epidural steroid injection produced substantial sustained pain relief regardless of pathology. In critique of the study, this small sample of patients was not enrolled at the same point in their disease. Due to these limitations, this potential Level II study provides Level III prognostic evidence that transforaminal CESI is an effective treatment for cervical radiculopathy in the majority of cases due to foraminal stenosis or cervical disc herniation.

Ferrante et al\(^2\) conducted a retrospective comparative study to identify factors that predict effectiveness of interlaminar CESI. Of the 100 patients included in the study, 80 were available for six month follow-up. Multiple regression analysis identified radicular symptoms as a predictor of better outcome after CESI. The authors concluded that CESI is more likely to be beneficial if a patient has radicular symptoms as opposed to axial neck pain. In critique, patients were not enrolled at the same point in their disease and no validated outcome measures were utilized. Due to these limitations, this potential Level II study provides Level III prognostic evidence that patients with cervical radiculopathy treated with CESI have a 62% probability of obtaining at least 50% pain relief and at least partial return to their activities of daily living.

Fish et al\(^3\) performed a retrospective case control study to identify MRI characteristics in patients with cervical radiculopathy that predict therapeutic response to intralaminar CESI. Of the 32 patients included in the study, 14 were diagnosed with cervical canal stenosis. At 20.5 week median follow-up, patients with cervical spine central canal stenosis had the worst NDI functional scores pre-treatment and had a significant response to treatment following CESI. The authors concluded that cervical spine MRI has a useful role to play in determining which patients would benefit from CESI. Central canal stenosis is a predictor of therapeutic response. In critique, this small sample of patients was not enrolled at the same point in their disease and follow-up was not standardized. This study provides Level III prognostic evidence that central canal stenosis identified on cervical spine MRI predicts a statistically significant improvement in NDI scores from cervical epidural steroid injection.
Kwon et al\textsuperscript{4} described a retrospective comparative study designed to determine predictors of short-term outcome following interlaminar CESI. Of the 76 patients included in the study and followed for two weeks, those with herniated disc were more likely to benefit from CESI than patients with cervical stenosis. The authors concluded that the radiographic cause of pain is a significant predictor of therapeutic response following cervical epidural. A significantly larger number of patients with herniated disc responded compared with those with central canal stenosis. In critique, patients were not enrolled at the same point in their disease and the study had a very short-term follow-up period. This study provides Level II prognostic evidence that CESI is associated with short-term benefit in the majority of patients with herniated cervical disc and radiculopathy symptoms.

Lin et al\textsuperscript{5} conducted a retrospective case control study to compare patients who requested surgery to those who did not after transfornaminal CESI. Seventy patients were followed for an average of 13 months. Patients who failed to improve with CESI and requested surgery were more likely to be younger (age < 50 years) and had a delay in first epidural from initial diagnosis. The authors concluded that two-thirds of patients with symptomatic cervical disc herniation may avoid surgery for at least one year by having a series of transfornaminal epidural steroid injections. In critique, this small sample of patients was not enrolled at the same point in their disease, follow-up was not standardized and treatment was not standardized. While avoidance of surgery is a valid outcome measure, it is subjective. This study provides Level III prognostic evidence that two-thirds of patients with cervical radiculopathy from cervical disc herniation might avoid surgery if treated with CESI. Patients older than 50 might be more likely to benefit from transfornaminal CESI.

Strub et al\textsuperscript{6} reported a retrospective case series of 161 patients designed to assess prognostic factors that influence outcome following interlaminar CESI. At ten day follow-up the authors found that patients with multilevel cervical spondylosis, radicular symptoms (to hand or finger) or those who had injection at the C7-T1 level were more likely to report substantial improvement following CESI. The authors concluded that interlaminar CESI is more effective in patients with multilevel cervical spondylosis or radiculopathy. In critique, the patients were not enrolled at the same point in their disease, no validated outcome measures were utilized and treatment was not standardized, with some patients receiving multiple injections. This study provides Level IV prognostic evidence that Interlaminar CESI is associated with short-term benefit in patients with cervical radiculopathy.

**Future Directions for Research**

A prospective comparative study of patients with documented single level cervical radiculopathy or cervical radicular pain treated with image-guided CESI within six weeks of the onset of symptoms would provide Level I prognostic evidence to address this question. Follow-up data should be obtained at four weeks and six months after final CESI with appropriate subgroup analysis to include nature of pathology, symptom duration prior to CESI, number of injections and description of standardized physical therapy prior to CESI.

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REFERENCES


ADDITIONAL REFERENCES REVIEWED


What are the risks associated with administration of cervical epidural steroid injections?

The risk of serious adverse events associated with administration of CESI appears low, but further higher quality studies are required.

Level of Evidence: IV

Many retrospective case reports describing complications following CESI were reviewed in order to address this question. On the basis of case series and case report, serious, sometimes catastrophic neurovascular injury including cortical, brainstem, or cerebellar infarction and death may complicate transforaminal epidural steroid injection with fluoroscopic or CT guidance. In addition, on the basis of case reports, spinal cord injury, acute subdural cervical hematoma and quadraplegia may complicate interlaminar epidural steroid injections. However, there is insufficient evidence to define the incidence of these serious adverse events. The following case reports provide Level IV therapeutic evidence that CESI can have catastrophic complications.

Beckman et al\(^1\) described a single case in which a patient suffered a cerebellar herniation into the foramen magnum and a right cerebellar infarction following transforaminal CESI. The patient underwent a posterior fossa craniectomy with resection of cerebellar tissue. The postoperative course was complicated by meningitis. The patient survived with residual diplopia and difficulties with short-term memory loss and concentration. The authors concluded that although transforaminal epidural steroid injections are an efficacious treatment for radicular syndromes, there can be catastrophic complications.

Brouwers et al\(^2\) reported a retrospective case report to describe the blood supply of the cervical spinal cord and suggest that an infarction resulted from an impaired perfusion of the major feeding anterior radicular artery of the spinal cord. Approximately one minute after the instillation of injectate, the patient developed flaccid paralysis and breathing difficulties. Thirty minutes later the patient's neurologic exam showed complete paralysis below the C3 level. The initial post-procedure MRI showed increased signal intensity of the spinal cord from C2 to T1. The following day MRI showed extensive infarction of the spinal cord. His hospitalization was complicated by pneumonias, and the following month the patient died from a stomach perforation. The authors concluded that in most patients collateral blood supply of the cervical spinal cord is sufficient, but as this case demonstrates, sometimes there is only one major feeding cervical anterior radicular artery. If this specific artery becomes iatrogenically occluded by a presumably spastic reaction or dissection on local injection, a devastating complication may be the result.

Hodges et al\(^3\) described two retrospective case reports involving serious complications following interlaminar CESI with IV sedation. Both cases resulted in spinal cord injury. The authors concluded that patients should be awake when cervical spine epidurals are administered.

Lee et al\(^4\) reported a complication following an attempted transforaminal CESI. Within two to three minutes of terminating the procedure the patient developed tetraplegia. At one year follow-up, the patient had weakness of the left arm with the development of a claw hand and refractory pain. The authors concluded that blind injection of contrast medium without fluoroscopic confirmation can be hazardous, resulting in spinal cord injury.

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Ludwig et al\textsuperscript{5} conducted a literature review and reported a single case of spinal cord infarction with CESI. Approximately ten minutes postprocedure the patient complained of weakness in the left arm and bilateral lower extremities. An initial MRI did not show spinal cord signal changes. A subsequent MRI 24 hours later showed evidence of spinal cord infarction from the odontoid to C4-5 level. The patient had incomplete tetraplegia and was classified as American Spinal Injury Association Impairment Scale score C, with loss of pain and temperature sensation and preservation of proprioception. The authors concluded that CESIs, despite careful fluoroscopic localization, carry a remote but devastating risk of vascular infarction to the spinal cord. The exact mechanism by which these infarctions occur remains unknown.

McMillan et al\textsuperscript{6} presented a case of acute cortical blindness and prolonged neurologic compromise complicating cervical transforaminal injection with acute disruption of the the blood brain-barrier demonstrated by MRI. Approximately 45 minutes after the injection of air and contrast, the patient was totally blind in both eyes. The initial MRI, two hours after the attempted procedure, showed bilateral parenchymal gadolinium enhancement in the occipital lobes and throughout the posterior intracranial circulation, indicating breakdown of the blood-brain barrier. Over the ensuing 24 hours the patient manifested obtundation, confusion, aphasia, swallowing dysfunction and bilateral blindness. The patient made gradual improvements over three weeks. He was discharged from the hospital at day 30 with mild short-term memory deficit and a persistent partial right homonymous hemianopia. The authors concluded that the neurologic deficits at four weeks may have been related to the persistent effects of air or other cerebral embolism, direct toxic effects of the contrast, or both.

Muro et al\textsuperscript{7} described a retrospective case report of a patient with an acute infarction of the cervical spinal cord after a multilevel transforaminal epidural steroid injection. Thirty minutes postprocedure, the patient had paresis in the upper extremities (left>right) and weakness in the lower extremities with some preservation of sensory function. Initial MRI did not show any significant lesions. Follow-up MRIs showed cervical spinal cord infarction extending to the cervicomedullary junction. At eight weeks she had gained strength in both upper extremities and in her right lower extremity and was ambulating independently with a walker. The authors concluded that although the incidence of neurologic dysfunction due to this procedure is low, the consequence can be devastating.

Reitman et al\textsuperscript{8} reported a complication involving an acute subdural cervical hematoma and quadraplegia following an uncomplicated fluoroscopically-guided interlaminar CESI. The patient underwent emergency decompressive surgery 11 hours after the injection and succumbed to complications related to the subdural hematoma 14 days after the ICESI. The authors concluded that spinal subdural hematomas can occur after CESI. The sequelae of cervical subdural hematoma after CESI are potentially devastating.

Rozin et al\textsuperscript{9} described a case report examining the death associated with a C7 nerve root block (transforaminal CESI). A CT scan showed a large hemorrhage around the brainstem, with obstructive hydrocephalus and extensive bleeding throughout the midbrain and pons into the lateral ventricles and basilar cisterns. Autopsy revealed dissection of the vertebral artery and focal petechial hemorrhage in the adventitia on the left side. A recent thrombosis was noted in the vertebral lumen. The authors concluded that it is up to the treating physician to take the the appropriate course of action to evaluate for the possibility of a ruptured artery.

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Suressh et al\textsuperscript{10} presented a case report and literature review of the potential complications of CT-guided transforaminal CESI. Immediately, post-procedure the patient was disoriented with loss of normal speech and hypertensive. Eight hours later the patient's condition deteriorated with the patient's Glasgow Coma Scale (GCS) declining from 14/15 to 6/15. A brain MRI revealed extensive high signal changes on T2 weighted images in the left cerebellum and left side of the brain stem, in the territory of the left vertebral artery. Forty-eight hours later, the condition improved and the GCS was 15/15. One month after the event the patient made a "progressive recovery." The authors concluded that the patient suffered an infarct, likely due to vasospasm because no dissection of the vertebral artery was evident on imaging.

Tiso et al\textsuperscript{11} described a case report involving a massive cerebellar infarction after uneventful selective cervical transforaminal block. Upon self-transfer from the C-arm table to the stretcher, the patient became unresponsive and hypoxic. Quadraparesis was evident one hour after injection. The patient underwent brainstem decompressive surgery and expired the following day. Pathology findings included bilateral cerebellar and left occipital cortex infarction. The authors concluded that corticosteroid particulate embolus during unintended intra-arterial injection may have resulted in the complication.

Wallace et al\textsuperscript{12} presented two cases demonstrating potentially devastating outcomes when a cervical SNRB is performed using fluoroscopic guidance. In the first patient, head CT showed marked edema of the pons and mid brain; a large hemorrhagic infarction within the pons, mid brain, cerebellum and thalami with intraventricular extension, subarachnoid hemorrhage and hydrocephalus. Postmortem findings included massive cerebral edema with perforation of the vertebra artery and dissection that extended into the basilar artery. Also, an intraluminal thrombus was noted within the dissected vertebral artery.

The patient suffered dissection of the left vertebral artery. Presenting symptoms were confusion, visual deficits, upper extremity paresis and facial weakness. The patient was heparinized and the symptoms resolved within 24 hours. CT of the head showed normal findings. Follow-up head CT one month after discharge was normal. The authors concluded that the technical complexity and potential complications of performing cervical nerve root blocks are underappreciated. Failure to recognize the potential for lethal complications combined with a belief that a procedure is simple can easily lead to the precipice of disaster.

Ziai et al\textsuperscript{13} described the clinical, radiological and autopsy findings of a 41 year old patient treated with a methylprednisolone CESI, who developed a fatal hemorrhagic brainstem infarction. Seven and one-half hours after the procedure the patient's condition had deteriorated. His speech was slurred and he had progressive weakness in all four extremities. He became unresponsive with nonreactive pupils. MRI showed ischemic infarction of the midbrain, pons and medulla, and left thalamus. MRI and MRA 24 hours later showed progression of the ischemia. The patient's condition did not improve and comfort care was instituted seven days postprocedure. Autopsy showed a small area of hemorrhage within the adventitia of the left vertebral artery around the C5-6 level and hemorrhagic necrosis of the basal thalamus, hypothalamus, midbrain, pons and medulla. The authors concluded that serious intracranial pathology from a CESI may occur despite the use of fluoroscopic guidance.
Minor adverse events, primarily vasovagal symptoms, may occur in 5-16.8% of patients treated with epidural steroid injections.

Level of Evidence: IV

Botwin et al\(^\text{14}\) reported a retrospective case series of 157 patients aimed at assessing complication rates following interlaminar cervical epidural injections. A 16.8% complication rate was reported at three week follow-up. All complications were minor and resolved. The authors concluded that interlaminar CESI is safe for patients with cervical radicular pain. This study provides Level IV therapeutic evidence that there is a 16.8% rate of minor complications following interlaminar CESI, with no serious or long-term complications identified in the study.

Derby et al\(^\text{15}\) described a retrospective case series comparing complication rates following interlaminar versus transforaminal CESI. The complication rate found was 0.52% following interlaminar CESI and 0.32% following transforaminal CESI. The authors concluded that the complication rate following interlaminar and transforaminal CESI is very low. This study provides Level IV therapeutic evidence that complication rates following interlaminar and transforaminal cervical epidural steroid injection are low and comparable between approaches when performed by experts.

Huston et al\(^\text{16}\) conducted a prospective case series to determine the complication rate associated with cervical and lumbar SNRB injections. Of the 211 patients included in the study, 37 received CESIs. The authors found no major complications and concluded that minor and transient side-effects occur following cervical spine epidural injection, but serious complications are rare. This study provides Level IV therapeutic evidence that serious complications did not occur in a small prospective series of patients following cervical spine epidural injection.

Pobiel et al\(^\text{17}\) conducted a prospective case series to evaluate immediate and 30 day complications following selective transforaminal cervical nerve root blockade. Of the 659 patients included in the study, 345 were available for 30 day follow-up. A 5% complication rate was reported, with no serious complications. The authors concluded that fluoroscopically-guided SNRB is a safe outpatient procedure with a low delayed and immediate complication rate. This study provides Level IV therapeutic evidence that fluoroscopically-guided transforaminal SNRB is a low-risk procedure.

Shellhas et al\(^\text{18}\) reported a retrospective case series including 4,612 patients to evaluate the safety and clinical utility of anterolateral cervical nerve root blockade. There was a 5% rate of a temporary exacerbation of pain, with no permanent neurological injuries reported. The authors concluded that fluoroscopically-guided CESI is safe when performed by experienced personnel. This study provides Level IV therapeutic evidence that fluoroscopically-guided transforaminal CESI is a low risk procedure.

Trentman et al\(^\text{19}\) described a retrospective case series including 249 patients to retrospectively compare the rate of vasovagal complications in translaminar cervical epidural steroid injections versus lumbar epidural injections. The risk of vasovagal complication following CESI was 8% compared to a 1% risk of complication following lumbar epidural injection. The authors concluded that the risk of vasovagal complications following

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CESI is substantially higher than the rate observed following lumbar injections. This study provides Level IV therapeutic evidence that there is an 8% risk of vasovagal complications with CESIs.

Waldman et al\textsuperscript{20} reported a prospective case series that assessed the complication rate following CESI in 215 patients. The authors reported that the complication rate within six weeks following CESI is low and concluded that cervical epidural injection is a safe modality. This study provides Level IV therapeutic evidence that cervical epidural injection appears to be relatively safe.

**Future Directions for Research**

A multicenter prospective comparative study (transforaminal vs. central epidural vs. control group, each stratified by medical comorbidities) defining the incidence of adverse effects of every severity would offer a higher level of evidence to answer this question.

**REFERENCES**


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ADDITIONAL REFERENCES REVIEWED


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**Practice and Coverage Considerations**

Due to the prevalence of cervical radicular pain, the increasing use of cervical epidural steroid injections (CESIs), and the potential confusion regarding appropriate patient selection, NASS proactively performed a comprehensive literature review to provide evidence-based recommendations regarding the use of CESIs in the treatment of cervical radicular pain.

For the purposes of the review, three specific questions commonly encountered in clinical practice were chosen:

1. Does the use of CESIs improve the outcomes of cervical radiculopathy/radiculitis?
2. Are there prognostic indicators that predict which patients are likely to benefit from CESIs?
3. What are the risks associated with administration of CESIs?

Based on this review, CESIs were found to be an appropriate treatment for patients suffering from radicular symptoms due to cervical disc herniation, central stenosis or neuroforaminal stenosis. The review also found that catastrophic complications of CESIs are rare. The Review and Recommendation Statement did not evaluate the use of CESIs in the treatment of axial neck pain, sympathetic pain, cervicogenic headaches or other cervical pain problems.

The review also did not address issues regarding the technical performance of these procedures or the appropriate number or frequency of injections. In order to address the latter issue, NASS performed a separate, less formal literature review and has developed some expert consensus recommendations to assist with answering practice and coverage questions related to these issues.

Our search identified little evidence that specifically addressed questions regarding the appropriate number or frequency of CESIs (or diagnostic cervical spinal nerve blocks) for the treatment of cervical radicular pain. However, based on the literature and expert opinion, a minimum of one or two CESIs would be very appropriate in the treatment of a specific episode of cervical radicular pain, with a maximum of four injections within six months, assuming there was a positive response and improvement seen with the previous injections. It should be noted, that both transforaminal CESIs and diagnostic cervical spinal nerve (root) blocks share the same Current Procedural Terminology (CPT) codes (64479-64480). Indications and appropriate use of these techniques, including total number and frequency of injections, are not necessarily the same. Given the potential for variable clinical circumstances, new or recurrent injury, and the utilization of therapeutic and diagnostic procedures in the same patient, an absolute limit of four CESIs per year would seem inappropriate and may overly restrict some patients from receiving necessary and reasonable care.

Although catastrophic complications associated with CESIs are rare, NASS recommends that specific technical modifications for the performance of CESIs be considered in an effort to reduce their occurrence. Some of these measures may include the use of non-particulate corticosteroid solutions for transforaminal epidural injections (as opposed to the more traditionally used particulate preparations) and routine use of fluoroscopic guidance for all cervical epidural injections.

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Appendices

Appendix A: Levels of Evidence/Grades of Recommendation

Appendix B: NASS Protocol for Literature Searches

Appendix C: CESI Literature Search Parameters
### APPENDIX A: Levels of Evidence/Grades of Recommendation

**Levels of Evidence For Primary Research Question**

As Adopted by the North American Spine Society January 2005

<table>
<thead>
<tr>
<th>Types of Studies</th>
<th>Levels of Evidence &amp; Grades of Recommendation</th>
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</table>
| **Therapeutic Studies** – Investigating the results of treatment | **Level I**
| **Level II**
| **Level III**
| **Level IV**
| **Level V**
| **Prognostic Studies** – Investigating the effect of a patient characteristic on the outcome of disease | **Economic and Decision Analyses** – Developing an economic or decision model |
| **Diagnostic Studies** – Investigating a diagnostic test | **Therapeutic Studies** – Investigating the results of treatment |
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#### Levels of Evidence For Primary Research Question

*As Adopted by the North American Spine Society January 2005*

**Types of Studies**

- **Therapeutic Studies** – Investigating the results of treatment
- **Prognostic Studies** – Investigating the effect of a patient characteristic on the outcome of disease
- **Diagnostic Studies** – Investigating a diagnostic test
- **Economic and Decision Analyses** – Developing an economic or decision model

**Level I**

- High quality randomized trial with statistically significant difference or no statistically significant difference but narrow confidence intervals
- Systematic Review of Level I RCTs (and study results were homogenous)
- High quality prospective study (all patients were enrolled at the same point in their disease with ≥ 80% follow-up of enrolled patients)
- Systematic review of Level I studies
- Testing of previously developed diagnostic criteria on consecutive patients (with universally applied reference "gold" standard)
- Systematic review of Level I studies

**Level II**

- Lesser quality RCT (e.g. < 80% follow-up, no blinding, or improper randomization)
- Prospective comparative study
- Systematic review of Level II studies or Level 1 studies with inconsistent results
- Retrospective study
- Untreated controls from an RCT
- Lesser quality prospective study (e.g. patients enrolled at different points in their disease or <80% follow-up.)
- Systematic review of Level II studies
- Development of diagnostic criteria on consecutive patients (with universally applied reference "gold" standard)
- Systematic review of Level II studies
- Sensible costs and alternatives; values obtained from many studies; with multiway sensitivity analyses
- Systematic review of Level I studies

**Level III**

- Case control study
- Retrospective comparative study
- Systematic review of Level III studies
- Case control study
- Study of non-consecutive patients; without consistently applied reference "gold" standard
- Systematic review of Level III studies
- Analyses based on limited alternatives and costs; and poor estimates
- Systematic review of Level III studies

**Level IV**

- Case Series
- Case series
- Case-control study
- Poor reference standard
- Analyses with no sensitivity analyses

**Level V**

- Expert Opinion
- Expert Opinion
- Expert Opinion
- Expert Opinion

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1. A complete assessment of quality of individual studies requires critical appraisal of all aspects of the study design.
2. A combination of results from two or more prior studies.
3. Studies provided consistent results.
4. Study was started before the first patient enrolled.
5. Patients treated one way (e.g. cemented hip arthroplasty) compared with a group of patients treated in another way (e.g. uncemented hip arthroplasty) at the same institution.
6. The study was started after the first patient enrolled.
7. Patients identified for the study based on their outcome, called “cases”; e.g. failed total arthroplasty, are compared to those who did not have outcome, called “controls”; e.g. successful total hip arthroplasty.
8. Patients treated one way with no comparison group of patients treated in another way.

Grades of Recommendation for Summaries or Reviews of Studies
As Adopted by the North American Spine Society January 2005

A: Good evidence (Level I Studies with consistent finding) for or against recommending intervention.
B: Fair evidence (Level II or III Studies with consistent findings) for or against recommending intervention.
C: Poor quality evidence (Level IV or V studies) for or against recommending intervention.
I: Insufficient or conflicting evidence not allowing a recommendation for or against intervention.

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APPENDIX B: Protocol for NASS Literature Searches

One of the most crucial elements of evidence analysis to support development of recommendations for appropriate clinical care or use of new technologies is the comprehensive literature search. Thorough assessment of the literature is the basis for the review of existing evidence, which will be instrumental to these activities. It is important that all searches conducted at NASS employ a solid search strategy, regardless of the source of the request. To this end, this protocol has been developed and NASS-wide implementation is recommended.

NASS research staff will work with the requesting parties and the NASS-contracted medical librarian to run a comprehensive search employing at a minimum the following search techniques:

1. A comprehensive search of the evidence will be conducted using the following clearly defined search parameters (as determined by the content experts). The following parameters are to be provided to research staff to facilitate this search.
   - Time frames for search
   - Foreign and/or English language
   - Order of results (chronological, by journal, etc.)
   - Key search terms and connectors, with or without MeSH terms to be employed
   - Age range
   - Answers to the following questions:
     - Should duplicates be eliminated between searches?
     - Should searches be separated by term or as one large package?
     - Should human studies, animal studies or cadaver studies be included?

   This search will encompass, at minimum, a search of PubMed, EMBASE, Cochrane and Web of Science. Additional databases may be searched depending upon the topic.

2. Search results with abstracts will be compiled by the medical librarian in Endnote software. The medical librarian typically responds to requests and completes the searches within two to five business days. Results will be forwarded to the research staff, who will share it with the appropriate NASS staff member or requesting party(ies). (Research staff has access to EndNote software and will maintain a database of search results for future use/documentation.)

3. NASS staff shares the search results with an appropriate content expert (NASS Committee member or other) to assess relevance of articles and identify appropriate articles to review.

4. NASS research staff will work with Galter library to obtain requested full-text articles for review.

5. NASS members reviewing full-text articles should also review the references at the end of each article to identify additional articles which should be reviewed, but may have been missed in the search.

Following this protocol will help ensure that NASS recommendations are (1) based on a thorough review of relevant literature; (2) are truly based on a uniform, comprehensive search strategy; and (3) represent the current best research evidence available. Research staff will maintain a search history in EndNote for future use or reference.

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APPENDIX C: CESI Literature Search Parameters

Databases Searched for All Questions

- PubMed
- Cochrane
- EMBASE Drugs and Pharmacology
- Web of Science

Search Parameters for All Questions

- Time frames for search: 1966-February 2010
- ENGLISH ONLY
- Age range: 18+
- HUMAN STUDIES ONLY

Search Strategy Implemented for Each Question

1. Does the use of CESIs improve the outcomes of cervical radiculopathy/radiculitis?


2. Are there prognostic indicators that predict which patients are likely to benefit from cervical epidural steroid injections?


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3. **What are the risks associated with administration of cervical epidural steroid injections?**


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Comprehensive Reference List


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