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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

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Abstract—Based on the available evidence, the Therapeutics and Technology Assessment subcommittee concluded that 1) epidural steroid injections may result in some improvement in radicular lumbosacral pain when assessed between 2 and 6 weeks following the injection, compared to control treatments (Level C, Class I–III evidence). The average magnitude of effect is small and generalizability of the observation is limited by the small number of studies, highly selected patient populations, few techniques and doses, and variable comparison treatments; 2) in general, epidural steroid injection for radicular lumbosacral pain does not impact average impairment of function, need for surgery, or provide long-term pain relief beyond 3 months. Their routine use for these indications is not recommended (Level B, Class I–III evidence); 3) there is insufficient evidence to make any recommendation for the use of epidural steroid injections to treat radicular cervical pain (Level U).

Chronic back pain and its associated disabilities represent an important health problem.[1] The rising prevalence of obesity may increase the impact of chronic back pain. The competitive nature of the modern workplace places individuals with less than perfect health and, in particular, those with painful conditions at a disadvantage. Workplace accommodation may not be an option for many occupations and, even where possible, is frequently linked with economic losses for employee and employer alike.

In 1998, individuals with back pain in the United States were estimated to have incurred total health care expenditures of $90.7 billion.[2] Inpatient care accounted for 31% of the expenditure, followed by expenditure for office-based visits (26%), prescription drugs (15.6%), and outpatient services (13.1%). Emergency department visits and home health visits each accounted for 3%. Of the $90.7 billion total expenditures incurred by these individuals, the expenditures attributable directly to the back pain totaled approximately $26.3 billion,[2] of which 42% were for office-based visits, 18% for outpatient services, 17% for inpatient care, 15% for prescription drugs, and 4% for emergency room visits. The estimated cost of treatments for spinal pain (medical therapy, epidural steroid injections, spinal cord stimulation, and intrathecal narcotics) for 1990 was at least $13 billion, growing by 7% per year.[3] Medicare part B claims in 1999 for 40.4 million covered individuals were $49.9 million for lumbar epidural steroid injections, $8.5 million for lumbar facet or peri-facet joint injections, and $5.6 million for cervical or thoracic epidural steroid injections.[4]

Low back pain may occur without or with radicular features (the latter often referred to as sciatica). In the strictest sense, sciatica refers to pain running down the posterior aspect of the lower extremity. A less restrictive usage to refer to lower back pain with

radiation is found in the literature reviewed for this report. A structural cause for sciatica, such as a herniated disc or foraminal stenosis, may or may not be found with investigations. Abnormalities on imaging may be seen in asymptomatic subjects, thus it may not be correct to infer a causal role for radiologic structural changes even if they are concordant with the distribution of sciatica.

Reports of epidural corticosteroid injections to treat sciatica date back to the 1950s.[5,6] Their use has increased over time despite limited quality data, as reflected by conflicting reviews of their efficacy and safety.[7-9] These reviews varied in terms of criteria for inclusion of patients, study design, types of interventions, outcome measures, and use of additional treatments. A recent review (2004) by the Technology Assessment Committee of the Institute of Clinical Systems Improvement (ICSI)[10] focused on fluoroscopically guided, transforaminal epidural steroid injections in radicular lumbar pain. Although it used an evidence-based approach, the rating system is different from that of the American Academy of Neurology (AAN). It concluded that, even though results based on limited data appeared to be promising, there was insufficient evidence to comment on the efficacy of transforaminal epidural steroid injections in radicular lumbar pain.[10]

A recent editorial[11] discussing the role of placebo-controlled trials emphasizes that pain treatments considered effective based on uncontrolled clinical observations or case studies may be found to be ineffective when tested within well-designed placebo-controlled studies. To avoid this error, higher quality evidence requires performance of studies incorporating rigorous case definition, use of controls (placebo or active), use of a standardized efficacy scale, masking of patient and evaluator regarding treatment, and gathering of safety data in different treatment arms. The data should permit calculation of the number of patients needed to treat in order to make one more patient better than what would be obtained with a control treatment (placebo or alternative active treatment).

A listing of important questions regarding epidural steroids appears in table 1. However, the number of high quality of studies was limited. Therefore, the question "What is the evidence to support use of epidural steroid injections in radicular lumbosacral pain to produce pain relief?" was dealt with first. Other endpoints considered within the higher quality studies so identified were considered, as were endpoints identified by reviewers for which there were high quality data.

Methods. *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

Table 1 *Epidural steroid use: Questions for consideration*

1. a. Who is being treated?

   Diagnosis for treatment

   Demographics (age, gender)

   b. Who should be treated?

2. Factors which predict outcome (good/bad)

   Factors which predict who should not be treated

3. What is the expected duration of benefit?

4. What is the appropriate technical approach?

   a. Direction of the needle

   b. Type of needle

   c. Dose of medication

   d. Fluoroscopy vs no fluoroscopy?

5. Competency of the treater?

6. Is the epidural injection sufficient, or should there be therapy of another kind with it?

   a. How does it compare to or add to other treatment modalities?

   b. Should it be combined with other treatment modalities?

7. Can we differentiate treatment for acute, subacute, chronic patients, and is there a difference in outcome?

8. How is efficacy measured?

   a. What measurement tools are used to measure efficacy?

   b. What measurement should be used to measure efficacy?

   c. How is success defined?

9. Is there evidence for efficacy?

10. Safety: How safe is this method of treatment? Are there any associated risks?

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.

Results. *Efficacy.* The search yielded 37 articles, 4 of which met the predetermined inclusion criteria.[12-15] These are summarized in an evidence table (table 2). Full review of a fifth article[16] 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 ICSI review[17,18] were summarized also in table 2. Some of the studies combined steroids with a local anesthetic, using the local anes-

Table 2 *Epidural steroids evidence table*

No.	Ref.	Study design, no. of patients, inclusion criteria, treatment evaluated, control	Measure of outcome; primary or secondary analysis	Findings (magnitude of effect, clinical significance)	Statistical significance	Class of evidence
1	12	1. Prospective, randomized, double-blind 2. 73 patients 3. Lumbar radicular pain syndromes; all had radiologic findings consistent with their symptoms or findings, and had failed to improve after 2 weeks of conservative treatment 4. One injection: 7 mL methylprednisolone acetate + procaine vs 7 mL saline + procaine	1. Short-term result: subjective improvement of 75% or more at 24 hours postinjection 2. Long-term result: subjective improvement of at least 75% at last contact (13–37 months, average 20 months postinjection); had not undergone laminectomy	1. No difference 2. No difference	1. $p = 0.2$ 2. NS	I
2	13	1. Prospective, randomized, double-blind 2. 23 patients 3. "Symptoms and signs of nerve root compromise"; signs not essential, radiculography not essential; duration of symptoms 1–13 months, average 4.7 4. Two caudal injections, one at entry and at 2 weeks, of 25 mL containing 80 mg triamcinolone acetonide in normal saline with 0.5% procaine HCl vs 25 mL normal saline 5. CAVEAT: Baseline imbalance of groups, SLRT worse in treated group, which reported less pain and symptom severity	1. Evaluation at baseline, 4 weeks, and 1 year 2. Subjective: Grogono and Woodgate symptomatology questionnaire (lifestyle); VAS (back pain); VAS (leg pain) Objective: angle of straight leg raising 3. Absolute scores of subjective variables and change of SLRT angle between visit and baseline (groups different on this, at baseline)	1. At 4 weeks: active treatment group improved, placebo had not; symptom severity 15.88 points (T) vs 13.7 points (P), VAS 38.5 mm to 16 mm (T) vs 49.2 mm to 45 mm (P); SLRT 43.8 degrees to 73.3 (T) vs 63.2 to 65 degrees (P) 2. At 52 weeks: symptom severity 16.6 points (T) vs 15.6 points (P); VAS 14.2 mm (T) vs 29.6 mm (P); SLRT 80.3 degrees (T) vs 74.1 degrees (P) 3. More withdrawal from study and more surgery in placebo group	1. Subjective measures: $p = 0.02$; SLRT: $p = 0.01$ 2. Subjective measures: NS; SLRT: $p = 0.01$, Wilcoxon rank-sum test used NS 3. NS	II
3	14	1. Prospective, randomized, double-blind 2. 158 patients 3. Symptoms of sciatica for >4 weeks and <1 year; CT evidence of a herniated disc at a level corresponding to symptoms; score >20 on Oswestry LBP disability questionnaire 4. 80 mg methylprednisolone acetate in 8 mL isotonic saline vs 1 mL isotonic saline. Injection repeated at 3 and 6 weeks if patient did not report overall marked improvement at the time	1. Primary outcome measure: Oswestry score at 3 months based on intention-to-treat 2. Outcome determined also at 3 and 6 weeks 3. Several secondary outcome measures	1. No difference in any outcome measure at 3 months 2. (a) At 6 weeks less leg pain on VAS: 11 mm difference in mean change, in favor of treatment group (95% CI 0.9 to 21.1); absolute scores: baseline: treatment group 65.6 mm, placebo 61.5 mm (SD 21.5 mm); 3 weeks: 44.9 mm (T), 49.1 mm (P); 6 weeks: not available; 3 months: 38.9 mm (T), 39.5 mm (P) Magnitude of effect (Cohen value) at 3–6 weeks: 0.4–0.5 (0.2 = small; 0.5 = moderate) (b) Reduced need for analgesics in treatment group between 3–6 weeks (median 50 vs 17) 3. Withdrawal 25% in placebo vs 15% in treatment group 4. Similar proportion of surgery at 12 months	1. NS 2. (a) $p = 0.03$ at 6 weeks; others = NS (b) $p = 0.01$ (not controlled for multiple comparisons) 3. NS 4. NS	I for primary outcome variable at 3 months; II for pain at earlier time points III for other outcome measures: multiple analyses; small mean effect size
4	15	1. Prospective, randomized, single-blind: patient aware, examiners of outcome blinded 2. 36 patients, age <50 years 3. Radicular lumbosciatic pain with concordant imaging (MRI) abnormality or disc herniation; positive SLRT <60 degrees; no previous surgery 4. 17 patients: three injections of 100 mg methylprednisolone in 10 mL bupivacaine 0.25% within first 14 days of hospitalization; both groups standard conservative treatment and a graded rehabilitation program	1. Evaluation at baseline and 2 and 6 weeks and 6 months after starting therapy 2. SLRT, VAS, Hannover Functional Ability Questionnaire	1. No difference between groups at 6 weeks and 6 months 2. Greater improvement in SLRT at 2 weeks in treated group: mean 33.5 degrees improved to 75 degrees vs 36.6 to 66	1. NS 2. $p = 0.03$ (not controlled for multiple comparisons)	III

Continued

Table 2 (continued)

No.	Ref.	Study design, no. of patients, inclusion criteria, treatment evaluated, control	Measure of outcome; primary or secondary analysis	Findings (magnitude of effect, clinical significance)	Statistical significance	Class of evidence
5	17*	1. Prospective, randomized, double-blind 2. 55 patients >21 years old 3. Selected from patients referred to 4 spine surgeons for radicular lumbar pain with radiologic confirmation of nerve root compression (disc herniation or central or foraminal stenosis) at 2 levels or less, refractory to (usually) at least 6 weeks of nonoperative treatment; previously operated patients included; extensive exclusions, including worker's compensation claim pending 4. Up to four injections: 1 mL containing 6 mg betamethasone + 1 mL 0.25% bupivacaine vs 1 mL 0.25% bupivacaine administered under fluoroscopic guidance with contrast injection for verification of localization	1. Treatment failure = patient opted to have surgery 2. North American Spine Society questionnaire at baseline, and, for patients who did not have surgery, at least 1 year following the injection 3. Final follow-up evaluation at 13 to 28 months (mean 23) following the first injection	1. 26/55 patients chose to have surgery 2. 8/28 patients treated with bupivacaine + betamethasone had surgery vs 18/27 of those treated only with bupivacaine 3. 36 patients had 1 injection, 10 had 2 injections, 6 had 3 injections, and 3 had 4 injections; only 6/19 patients with multiple injections had surgery (injection composition not stated) 4. A trend toward a decrease in neurologic symptoms from baseline to final follow-up in patients who avoided surgery; subgroup analyses provided without numbers of patients or magnitudes of effects	1. N/A 2. $p < 0.004$	III
6	18*	1. Prospective, randomized, triple-blind 2. 80 patients, age 44 ± 13 years in each group (from 277 candidates of whom 171 were considered eligible) 3. Unilateral pain radiating dermatomally from back to below the knee; 3–28 weeks; leg pain ≥ back pain; signs not needed; MRI and EMG performed—no report how factored; extensive exclusions, including previous surgery, application for early retirement, depression 4. Methylprednisolone + bupivacaine vs normal saline, under fluoroscopy, following contrast injection to confirm localization; back school instructions at 2 weeks' follow-up, pain medication and physiotherapy if needed	1. Primary outcome variable = leg pain measured on 100 mm VAS; 15 mm mean difference between groups considered clinically meaningful; mean difference adjusted for differences in baseline variables (AMD); evaluation at baseline, immediately after the injection, and 2 weeks, 1, 3, 6, and 12 months after the injection 2. Secondary: back pain on 100 mm VAS; disability on Oswestry questionnaire; quality of life on Nottingham Health Profile; SLRT; lumbar flexion 3. Economic analysis	1. For leg pain: immediate effect (AMD 11.9 mm) and 2 week effect (AMD 12.5 mm) favor steroids; at 4 weeks and 3 months, no difference; at 6 months steroid arm worse (AMD 16.2 mm); at 12 months, no difference 2. For back pain: steroid group worse at 3 months (AMD 12.2 mm) and 6 months (AMD 13.5 mm); no difference at other times 3. Costs equal in both groups; 18 patients operated in steroid group vs 15 in saline group	1. $p = 0.02$ (immediate, 2 weeks); $p = 0.003$ (6 months); otherwise NS 2. $p = 0.02$ at 3 months; $p = 0.03$ at 6 months; otherwise NS 3. NS	I

*Identified within the ICSI review.[10] See discussion in text.

NS = not significant; VAS = Visual Analogue Scale; T = treatment group; P = placebo group; "to" = "changed to"; SLRT = Straight Leg Raising Test; LBP = low back pain; N/A = not applicable; AMD = difference between treatment groups in mean change from baseline, adjusted for differences in baseline variables.

thetic as a control or normal saline as the control, while others compared steroids to normal saline.

Safety. The most common complication is a transient headache whether or not associated with identifiable dural puncture.[14] More serious complications, summarized in a 1996 review,[19] 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).[19] A retroperitoneal hematoma was reported in one patient on anticoagulant therapy who received a fluoro-

scopically guided transforaminal injection of steroids.[18] 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.[20] No major neurologic complications (spinal hematomas) were encountered in a series of 1,035 individuals who received epidural steroid injections while on antiplatelet therapy.[21] 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.[21] 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.[22]

The role of practitioner experience and radiologic confirmation of needle placement cannot be determined based on these reports. The results of the one high quality study with radiologic confirmed needle placement did not provide direct comparison of techniques. Therefore, the utility of, or need for, fluoroscopic confirmation of needle placement is unclear.

Discussion. *Comparison to the results of the ICSI review.* This evidence-based review focusing specifically on fluoroscopically guided transforaminal epidural injections[10] identified two studies it considered of high quality, which had not been identified by the Medline searches. One article studied pain relief,[18] and we concurred that it was of high quality (Class I evidence). Its results were consistent with studies performed without radiologic guidance. The second article used avoidance of surgery as its primary outcome measure.[17] However, methodologic limitations resulted in a lower rating under our system (Class III evidence). The limitations included small sample size, the highly selected sample due to self-selection of participants, imprecise case definition, lack of control for possible confounding factors, and insufficient information about why subjects proceeded to surgery. Its findings favoring efficacy, while concordant with those of a previously identified article,[13] were discordant from those of articles that were rated higher, that showed no impact on utilization of surgery.[14,18] The lack of overlap between high quality articles found using the two search strategies resulted from use of different search terms. The ICSI review did not retrieve articles that did not use fluoroscopy, and the high quality article reporting results with transforaminal, peri-radicular injections using fluoroscopy did not incorporate the terms we had used in our original search. However, the results with the two search strategies were similar, strengthening the validity of our conclusions and recommendations.

Principal findings, in clinical perspective. With regards to the primary question of this review, amelioration of pain, the findings of the four high quality studies[12-14,18] are internally consistent, showing the following efficacy pattern compared to a control group: no efficacy at 24 hours[12]; some efficacy at 2 to 6 weeks[13,14,18]; no difference[14] or rebound worsening at 3 months[18] and 6 months[18]; and no difference at 1 year.[13,18] The immediate postinjection amelioration of leg, but not back pain, may have been due to the local anesthetic with which the steroid was mixed in one study.[18]

These results support the individual perception of benefit of epidural steroids, expressed in terms of short-term symptomatic relief, a positive result in

and of itself. However, the average effect difference (advantage of steroids over control treatment) was small, usually falling short of the value proposed as a clinically meaningful average difference[18]—15 mm on the 100 mm visual analogue pain scale. Other investigators have shown that, at the individual level, an optimal value for a clinically meaningful change on a 0 to 10 pain intensity scale is a 2-point absolute change (or a 33% relative change).[23-25] However, the available studies did not express the magnitude of relief in terms of the percent of patients attaining a clinically meaningful response, and thus do not permit calculations of number of patients needed to treat in order to benefit one patient.

These results are consistent with the results of a study comparing 43 patients treated with epidural methylprednisolone applied during unilateral lumbar discectomy with matched historical controls that showed reduced need for narcotic and non-narcotic pain medications and muscle relaxants during the postoperative period, and shorter hospital stay in treated patients (an average of 2.72 days in treated patients vs 4.35 days in the untreated patients).[26] Reported complications of epidural steroid injections are usually minor and transient: the most frequent is a transient headache. Reported major complications are rare (aseptic meningitis, arachnoiditis, bacterial meningitis, epidural abscess, and conus medullaris syndrome), and may result from subarachnoid, rather than epidural injection. There may be underreporting of complications, and the reported safety track record of experienced practitioners with large volumes may not reflect the track record of smaller volume or less experienced practitioners. These results do not answer most of the other questions listed in table 1. With regards to the specific question of avoidance of surgery, the data on face value are conflicting, with the better designed studies showing no benefit to epidural steroids. The data from the less well-designed studies are harder to interpret and generalize, as are data from uncontrolled clinical settings. The data do not permit inferring if surgery is avoided due to the treatment effect of injected steroids, due to placebo effect, or because the treatment "buys time" for a natural history of improvement.[10] The data do not address how epidural steroid injections might compare to other treatment modalities and the role of patient and provider characteristics, including temperament and pain tolerance, in selecting among various treatment options. The recommendations gave greater weight to the data from the better designed studies, showing that epidural steroid injections did not result in less surgery.

However, an uncontrolled study[27] with partial follow-up of treated patients has identified factors that predict poor outcome: 1) greater number of previous treatments for pain; 2) more medications taken; 3) pain not necessarily increased by activity; 4) pain increased by coughing. Factors that predict no benefit 1 year after treatment include 1) pain does

not interfere with activities; 2) unemployment due to pain; 3) normal straight leg raising tests before treatment; 4) pain not decreased by medication. Better designed studies are needed to confirm these observations, and express them in contemporary terms of numbers needed to treat, relative to presence or absence of predictive factors for poor outcome.

Limitations. This review is limited by its inability to compare all techniques and all treatment approaches. However, the findings in terms of pain relief and some of the secondary measures are similar for the earlier studies and for those that used fluoroscopy and transforaminal injections. This review did not assess issues of frequency of injection or dosage, and did not evaluate operator experience, which was implied to be high in all the published reports. The generalizability of the findings is limited. The focus on pain relief, guided by the chief indication for which epidural steroid injections are used, is a limitation, compared to using improvement of function as the primary outcome variable. However, it frames the subjective impressions of patients and providers in evidence-based terminology that may guide the future evaluation of this treatment modality.

Recommendations and conclusions. 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).

Recommendations for future research.
1. Further studies of the efficacy of epidural steroids for radicular lumbosacral pain should be well-designed, meeting the following criteria: a) clear case definition; b) clear measures of outcome using standardized tools, with function as the primary measure and clinically meaningful improvement in pain[23-25] as a secondary measure; c) use of a control group (placebo or active); d) prospective design; e) randomization; f) double-blind study design, so that neither patient nor assessor of measure of outcome knows the treatment arm; or triple-blind, if physician administering the epidural steroids also does not know what treatment is administered; g) adequate power; and h) adequate statistical analysis.
2. Studies of use of epidural steroids to treat radicular cervical pain or non-radicular low back or cervical pain should also be designed rigorously, meeting similar criteria.
3. The principal questions to be answered are as follows:
   (a) What is the degree of efficacy, expressed in terms of magnitude of effect, duration of effect, and percent of patients who achieve clinically meaningful improvement, in comparison to alternative treatments?
   (b) Using a controlled design: are there predictors of lack of efficacy or poor efficacy? Consider studying first patients without putative predictors of poor efficacy.
   (c) How many treatments are appropriate, and at what intervals?
   (d) How frequent are complications, and what are they?
4. Initially, it will be necessary to standardize some of the variables reflected in the questions in table 1, such as a specific technical approach, the minimal competency of the treating physician, and utilization of additional therapies.
5. Subsequently, research can be directed to evaluate the role of these variables. In particular, different techniques will need to be assessed using standardized methodology.

Mission statement of TTA. The Therapeutics and Technology Assessment Subcommittee (TTA) produces evidence-based statements that assess the safety, utility, and effectiveness of new, emerging, or established therapeutic agents or technologies in the field of neurology. These are developed through a rigorous process of defining the topic, evaluating and rating the quality of the evidence, and translating the conclusions of the evidence into practical recommendations that can help to guide the practice of Neurology.

Disclaimer. This statement is provided as an educational service of the American Academy of Neurology. 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.

Conflict of interest statement. The American Academy of Neurology 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.

Appendix 1

Therapeutics and Technology Assessment subcommittee members: Yuen T. So, MD, PhD (Co-Chair); Janis Miyasaki, MD, FAAN (Co-Chair); Douglas S. Goodin, MD (ex-officio); Carmel Armon, MD, MHS, FAAN (ex-officio); Richard M. Dubinsky, MD, MPH, FAAN; Mark Hallett, MD, FAAN; Cynthia L. Harden, MD; Michael A. Sloan, MD, MS, FAAN; James C. Stevens, MD, FAAN; Fenwick T. Nichols, III, MD; Kenneth J. Mack, MD, PhD; Paul W. O'Connor, MD; Vinay Chaudhry, MD, FAAN.

Appendix 2

AAN 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 cross-overs 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.

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* 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).

Appendix 3

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.

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