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Health Policy Review

Reassessment of Evidence Synthesis of Occupational Medicine Practice Guidelines for Interventional Pain Management

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Background: Appropriately developed practice guidelines present statements of best practice based on a thorough evaluation of the evidence from published studies on the outcomes of treatments, which include the application of multiple methods for collecting and evaluating evidence for a wide range of clinical interventions and disciplines. However, the guidelines are neither infallible, nor a substitute for clinical judgment. While the guideline development process is a complex phenomenon, conflict of interest in guideline development and inappropriate methodologies must be avoided.

It has been alleged that the guidelines by the American College of Occupational and Environmental Medicine (ACOEM) prevent injured workers from receiving the majority of medically necessary and appropriate interventional pain management services. An independent critical appraisal of both chapters of the ACOEM guidelines showed startling findings with a conclusion that these guidelines may not be applied in patient care as they scored below 30% in the majority of evaluations utilizing multiple standardized criteria.

Objective: To reassess the evidence synthesis for the ACOEM guidelines for the low back pain and chronic pain chapters utilizing an expanded methodology, which includes the criteria included in the ACOEM guidelines with the addition of omitted literature and application of appropriate criteria.

Methods: For reassessment, randomized trials were utilized as it was in the preparation of the guidelines. In this process, quality of evidence was assessed and recommendations were made based on grading recommendations of Guyatt et al. The level of evidence was determined utilizing the quality of evidence criteria developed by the U.S. Preventive Services Task Force (USPSTF), as well as the outdated quality of evidence criteria utilized by ACOEM in the guideline preparation. Methodologic quality of each individual article was assessed utilizing the Agency for Healthcare Research and Quality (AHRQ) methodologic assessment criteria for diagnostic interventions and Cochrane methodologic quality assessment criteria for therapeutic interventions.

Results: The results of reassessment are vastly different from the conclusions derived by the ACOEM guidelines. The differences in strength of rating for the diagnosis of discogenic pain by provocation discography and facet joint pain by diagnostic facet joint nerve blocks is established with strong evidence. Therapeutic cervical and lumbar medial branch blocks and radiofrequency neurolysis, therapeutic thoracic medial branch blocks, cervical interlaminar epidural steroid injections, caudal epidural steroid injections, lumbar transforaminal epidural injections, percutaneous and endoscopic adhesiolysis, and spinal cord stimulation qualified for moderate to strong evidence. Additional insight is also provided for evidence rating for intradiscal electrothermal therapy (IDET), automated percutaneous disc decompression, and intrathecal implantables.

Conclusion: The reassessment and reevaluation of the low back and chronic pain chapters of the ACOEM guidelines present results that are vastly different from the published and proposed guidelines. Contrary to ACOEM's conclusions of insufficient evidence for most interventional techniques, the results illustrate moderate to strong evidence for most diagnostic and therapeutic interventional techniques.

Key words: Guidelines, evidence-based medicine, systematic reviews, ACOEM, interventional pain management, interventional techniques, guideline development, workers' compensation, chronic pain guidelines, low back pain guidelines

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Clinical practice guidelines present statements of best practice based on a thorough evaluation of the evidence from published studies on the outcomes of treatment. In appropriately developed guidelines, multiple methods must be used for collecting and evaluating evidence for a wide range of clinical interventions and disciplines to an array of interventional procedures, both diagnostic and therapeutic (1). The guidelines must be based on the practice of evidence-based medicine, which was originally defined as evidence-based practice (2), and is based on 4 basic contingencies: 1) the recognition of the patient's problem and the construction of a structured clinical question, 2) the ability to efficiently and effectively search the medical literature to retrieve the best available evidence to answer the clinical question, 3) critical appraisal of the evidence, and 4) integration of the evidence with all aspects of decision-making to determine the best clinical care of the patient. The National Health and Medical Research Council of Australia (2), Shaneyfelt et al (3), the American Medical Association (AMA) (4), and the Institute of Medicine (IOM) (5) have described multiple criteria for development of the guidelines. Consequently, appropriately developed guidelines incorporate validity, reliability, reproducibility, clinical applicability, flexibility, clarity, development through a multidisciplinary process, scheduled reviews, and documentation (5,6). Evidence-based clinical practice guidelines are statements developed to improve the quality of care, patient access, treatment outcomes, appropriateness of care, efficacy and effectiveness, and achieve cost containment by improving the cost benefit ratio.

Guidelines are sponsored by various organizations, most commonly by specialty societies. The National Guideline Clearinghouse and the Agency for Healthcare Research and Quality (AHRQ) (7) provide an extensive list of guidelines which continues to expand. Guidelines are developed based on the evidence and opinion. Thus, they are neither infallible nor a substitute for clinical judgment (8). Guidelines differ from systematic reviews in that guidelines recommend what should and should not be done in specific clinical circumstances (2-22).

The guideline development process is complex. Thus, guidelines could be extremely controversial, even when developed by governmental agencies. However, the best guidelines are considered to be the ones from the U.S. Preventive Services Task Force (USPSTF), the Advisory Committee on Immunization Practices, the National Academies of Science, Centers for Disease Control and Prevention, which are all in the U.S., and the National Institute for Clinical Excellence (NICE) in the United Kingdom and the World Health Organization (WHO). Guidelines often elicit controversy for numerous reasons including the type of recommendations and the restrictions on practice patterns. In fact, Congress eliminated the Agency for Health Care Policy and Research (AHCPR) in 1995 after the development of acute low back pain guidelines (23). The AHCPR, over the years, issued 19 guidelines at a cost of $750 million (over $40 million per guideline) (23,24).

National medical specialty societies are a major source of guideline development in the United States. As early as 1938, the American Academy of Pediatrics published its guidelines for the treatment of infectious disease (25). This effort by the American Academy of Pediatrics was supported by the AMA as an alternative to expenditure targets. Further, the AMA established its own organizational structure for the development of clinically sound and relevant guidelines through the forum on practice parameters in 1989 (4,26).

Conflicts of interest in guideline development and inappropriate methodologies have been questioned based on pharmaceutical and medical device company sponsorship, when members of the guideline committees have a substantial financial association with an industry, or there is a relationship between the developing organization and industry, or, finally, when there is no relevant clinical relationship or expertise on the part of the developers of the guidelines (2-9,27-44). It has been argued that public disclosure of sponsorship and of the financial associations of committee members along with other adequate safeguards and rules to prevent sponsors from influencing the selection of panel members and the content of the guidelines be mandatory. It is maintained that practice recommendations will invariably be viewed with skepticism unless corporate sponsorship and financial relationships as well as experts with financial ties and experts promoting their own specialty while making decisions on other specialties are completely avoided. At present, the financial ties between guidelines panels and industry appear to be extensive. In fact, a survey of 685 disclosure statements by authors of guidelines concerning medications found that 35% declared a potential financial conflict of interest (39).

The American College of Occupational and Environmental Medicine (ACOEM) published a series of

guidelines beginning in 1997 with the latest revisions in 2007 and 2008 for multiple chapters including low back pain and chronic pain (27,33,34). It has been alleged that these guidelines prevent injured workers from receiving the majority of the medically necessary and appropriate interventional pain management services (30,35,37,38,40-44).

An independent critical appraisal of the low back pain and chronic pain chapters of the ACOEM guidelines (44) showed startling findings with a conclusion that these guidelines should not be applied in patient care because they scored below 30% in the majority of evaluations utilizing standardized criteria developed by Appraisal of Guidelines Research and Evaluation (AGREE) (45,46), Shaneyfelt et al's criteria (3), IOM criteria (5), and multiple attributes described by AMA (4). This evaluation (44) concluded that based on the evaluation of the AGREE instrument (45,46), scores were low in 5 of the 6 domains and also in the global assessment (44). The ACOEM guidelines met only one of the 6 attributes described by AMA (4) and 2 of the 8 key attributes described by IOM (5), and 7 of the 25 criteria by Shaneyfelt et al (3).

Consequently, the reassessment of evidence synthesis for the ACOEM guidelines for the low back pain and chronic pain chapters is undertaken utilizing an expanded methodology, which includes the criteria included in the ACOEM guidelines and also with the addition of omitted literature and the application of appropriate criteria.

Methods

For reassessment of the low back pain and chronic pain chapters of the ACOEM guidelines (33,34), the evidence from randomized trials was utilized as it was utilized by the ACOEM guideline preparers. This methodology is not considered the best scientific or comprehensive approach available to evidence synthesis. In this approach there is no opportunity to apply any other methodology, including consensus and expert opinions, if an evidence-based approach from randomized trials failed to provide adequate levels of evidence. Yet, ACOEM utilized this narrowly focused consensus. Multiple approaches for evidence synthesis have been described in separate publications (1,2,4,5,8,19,22,47,48).

Sequential Process and Grading of Recommendations

In guideline synthesis, grading the strength of recommendations and quality of evidence in clinical guidelines is crucial (19). The GRADE Working Group (grading of recommendations, assessment, development, and evaluation) recommended grading quality and strength of evidence (20). The steps in this approach were to make sequential judgments about the quality of evidence of studies for each important outcome, which outcomes were critical to a decision, the overall quality of evidence across those critical outcomes, the balance between benefits and harms, and the strength of recommendations. Thus, the GRADE system enables more consistent judgments, and communication of said judgments, resulting in better informed choices in health care. Table 1 illustrates the sequential process for developing guidelines (20).

Guyatt et al (19) developed an optimal grading system based on the philosophy that guideline panels should make recommendations to administer or not administer an intervention on the basis of a trade-off between benefits on the one hand and risks, burdens, and potential costs on the other. They provided recommendations at 2 levels: strong and weak as illustrated in Table 2. A Grade 1 recommendation (strong) is if guideline panels are very certain that benefits do or do not outweigh the risks and burdens. A Grade 2 (weak) recommendation is if panels think that the benefits and the risks and burdens are finely balanced or applicable and uncertainties exist above the magnitude of the benefits and risks. However, guideline panels must consider a number of factors in grading recommendations including 1) methodologic quality of the evidence reporting estimates of likely benefit and likely risk, inconvenience, and costs, 2) importance of the outcome, 3) magnitude of the treatment effect, 4) estimate of treatment effect, 5) risks associated with therapy, 6) burden of therapy, 7) risk of target event, 8) costs, and finally 9) circumstances, patients' or societal values.

Level of Evidence

While there is no universally accepted approach to developing and presenting guidelines, the most rigorous approach in widespread use was developed by the AHRQ USPSTF (21). This quality of evidence developed by AHRQ includes 3 levels, as illustrated in Table 3, varying from evidence obtained from at least one properly randomized controlled trial to opinions of respected authorities. Quality of evidence utilized in the American Society of Interventional Pain Physicians (ASIPP) evidence synthesis ranged from Level I to Level

Table 1. *Sequential process for developing guidelines as described by Atkins et al (20).*

First steps
1. *Establishing the process*—For example, prioritizing problems, selecting a panel, declaring conflicts of interest, and agreeing on group processes
Preparatory steps
2. *Systematic review*—The first step is to identify and critically appraise or prepare systematic reviews of the best available evidence for all important outcomes
3. *Prepare evidence profile for important outcomes*—Profiles are needed for each subpopulation or risk group, based on the results of systematic reviews, and should include a quality assessment and a summary of findings
Grading quality of evidence and strength of recommendations
4. *Quality of evidence for each outcome*—Judged on information summarized in the evidence profile and based on the criteria
5. *Relative importance of outcomes*—Only important outcomes should be included in evidence profiles. The included outcomes should be classified as critical or important (but not critical) to a decision
6. *Overall quality of evidence*—The overall quality of evidence should be judged across outcomes based on the lowest quality of evidence for any of the critical outcomes
7. *Balance of benefits and harms*—The balance of benefits and harms should be classified as net benefits, trade-offs, uncertain trade-offs, or no net benefits based on the important health benefits and harms
8. *Balance of net benefits and costs*—Are incremental health benefits worth the costs? Because resources are always limited, it is important to consider costs (resource utilization) when making a recommendation
9. *Strength of recommendation*—Recommendations should be formulated to reflect their strength—that is, the extent to which one can be confident that adherence will do more good than harm
Subsequent steps
10. *Implementation and evaluation*—For example, using effective implementation strategies that address barriers to change, evaluation of implementation, and keeping up to date

Adapted from Atkins et al. Grading quality of evidence and strength of recommendations. *BMJ* 2004; 328:1490 (20).

V with Level I being conclusive with research-based evidence including multiple relevant and high-quality scientific studies or consistent reviews of meta-analysis and Level V being indeterminate with opinions of respected authorities (Table 4) (1,10,11). In contrast, the authors of the ACOEM guidelines have utilized an outdated AHCPR hierarchy of evidence (dismissed by Congress in 1995), which carries the disclaimer not for patient care as illustrated in Table 5 (33,34). For uniformity purposes in this analysis, we will continue to use the same evidence categories, as utilized in the ACOEM guidelines. However, in this analysis, quality of evidence developed by AHRQ USPSTF (21) as shown in Table 3 and the grading of recommendations as illustrated in Table 2 is also taken into consideration.

Inclusion Criteria

Types of Studies

Included in the analysis are randomized trials for therapeutic interventional procedures and non-randomized studies for diagnosis and screening.

Types of Participants

Subjects with pain of spinal origin.

Types of Interventions

All types of interventional techniques with well described methodology and appropriate inclusion criteria.

Types of Outcome Measures

Pain relief and functional status improvement with at least 6 to 12 month follow-up for therapeutic interventions.

Outcome Measurements

Pain relief of short-term (≤ 6 months) and long-term (> 6 months) is the primary outcome measure for all interventions, except for discectomy and implantables, for which > 1-year relief is considered as long-term. Secondary outcomes are functional or psychological improvement, improvement in work status, and complications.

Table 2. *Grading recommendations of Guyatt et al (19).*

Grade of Recommendation/ Description	Benefit vs Risk and Burdens	Methodological Quality of Supporting Evidence	Implications
1A/strong recommendation, high-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	RCTs without important limitations or overwhelming evidence from observational studies	Strong recommendation, can apply to most patients in most circumstances without reservation
1B/strong recommendation, moderate quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	RCTs with important limitations (inconsistent results, methodological flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies	Strong recommendation, can apply to most patients in most circumstances without reservation
1C/strong recommendation, low-quality or very low-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	Observational studies or case series	Strong recommendation but may change when higher quality evidence becomes available
2A/weak recommendation, high-quality evidence	Benefits closely balanced with risks and burden	RCTs without important limitations or overwhelming evidence from observational studies	Weak recommendation, best action may differ depending on circumstances or patients' or societal values
2B/weak recommendation, moderate-quality evidence	Benefits closely balanced with risks and burden	RCTs with important limitations (inconsistent results, methodological flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies	Weak recommendation, best action may differ depending on circumstances or patients' or societal values
2C/weak recommendation, low-quality or very low-quality evidence	Uncertainty in the estimates of benefits, risks, and burden; benefits, risk, and burden may be closely balanced	Observational studies or case series	Very weak recommendations; other alternatives may be equally reasonable

Adapted from Guyatt G et al. Grading strength of recommendations and quality of evidence in clinical guidelines. Report from an American College of Chest Physicians task force. *Chest* 2006; 129:174-181 (19).

Table 3. *Quality of evidence developed by AHRQ.*

I	**Evidence obtained from at least one properly randomized controlled trial.**
II-1	**Evidence obtained from well-designed controlled trials without randomization.**
II-2	**Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.**
II-3	**Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.**
III	**Opinions of respected authorities, based on clinical experience descriptive studies and case reports or reports of expert committees.**

Adapted from Berg Ao, and Allan JD. Introducing the third US Preventative Service Task Force. *AM J Prev Med* 2001; 20:21-35.(21).

Table 4. *Designation of levels of evidence as used in evidence-based guidelines by ASIPP.*

Level I	Conclusive: Research-based evidence with multiple relevant and high-quality scientific studies or consistent reviews of meta-analyses
Level II	Strong: Research-based evidence from at least one properly designed randomized, controlled trial; or research-based evidence from multiple properly designed studies of smaller size; or multiple low quality trials
Level III	Moderate: a) Evidence obtained from well-designed pseudorandomized controlled trials (alternate allocation or some other method); b) evidence obtained from comparative studies with concurrent controls and allocation not randomized (cohort studies, case-controlled studies, or interrupted time series with a control group); c) evidence obtained from comparative studies with historical control, 2 or more single-arm studies, or interrupted time series without a parallel control group
Level IV	Limited: Evidence from well-designed non-experimental studies from more than one center or research group; or conflicting evidence with inconsistent findings in multiple trials
Level V	Indeterminate: Opinions of respected authorities, based on clinical evidence, descriptive studies, or reports of expert committees

Adapted and modified from Boswell MV et al. Interventional techniques: Evidence-based practice guidelines in the management of chronic spinal pain. *Pain Physician* 2007; 10:7-111 (1).

Table 5. *Outdated quality of evidence criteria utilized by ACOEM (33), adapted and modified from AHCPR (23).*

A	**Strong evidence-base:** Two or more high-quality studies[i].
B	**Moderate evidence-base:** At least one high-quality study or multiple moderate-quality studies[ii] relevant to the topic and the working population.
C	**Limited evidence-base:** At least one study of moderate quality.
I	**Insufficient Evidence:** Evidence is insufficient or irreconcilable.

ii. For therapy and prevention, randomized controlled trials (RCTs) with narrow confidence intervals and minimal heterogeneity.
For diagnosis and screening, cross sectional studies using independent gold standards.
For prognosis, etiology, or harms, prospective cohort studies with minimal heterogeneity.
ii. For therapy and prevention, a well-conducted review of cohort studies. For prognosis, etiology, or harms, a well-conducted review of retrospective cohort studies or untreated control arms of RCTs.

Review Methods

The quality of individual articles was evaluated using criteria from the AHRQ publication (47) for diagnostic studies (Table 6), and Cochrane review criteria (49-53) for randomized trials (Table 7). In evidence synthesis, only the studies scoring 50 or above were utilized. The ACOEM guidelines utilized an 11-item system without weights assigned (Table 8). Thus, to arrive at 100, the ACOEM assigned score was multiplied by a factor of 9.1, resulting in a score close to 100 (11 x 9.1 = 100.1).

Literature Search/Data Extraction

Review of the literature was based on the ACOEM guidelines, multiple systematic reviews, health technology assessments, and guidelines (1,33,34,54-87), and incorporation of other literature.

Table 6. *Modified AHRQ methodologic assessment criteria for diagnostic interventions.*

CRITERION	Weighted Score
1. Study Population	**30**
• Subjects similar to populations in which the test would be used and with a similar spectrum of disease	
2. Adequate Description of Test	**15**
• Details of test and its administration sufficient to allow for replication of study	
3. Appropriate Reference Standard	**20**
• Appropriate reference standard (gold standard) used for comparison	10
• Reference standard reproducible	10
4. Blinded Comparison of Test	**20**
• Evaluation of test without knowledge of disease status, if possible	10
• Independent, blind interpretation of test and reference	10
5. Avoidance of Verification Bias	**15**
• Decision to perform reference standard not dependent on results of test under study	
TOTAL SCORE	**100**

Adapted and modified from West S et al. Systems to Rate the Strength of Scientific Evidence, Evidence Report, Technology Assessment No. 47. AHRQ Publication No. 02-E016 (47).

Table 7. *Modified and weighted Cochrane methodologic quality assessment criteria as described by Koes et al (51).*

CRITERION		Weighted Score
1. Study population		**35**
A	Homogeneity	2
B	Comparability of relevant baseline characteristics	5
C	Randomization procedure adequate	4
D	Drop-outs described for each study group separately	3
E	≤ 20% loss for follow-up	2
	≤ 10% loss for follow-up	2
F	> 50 subject in the smallest group	8
	> 100 subjects in the smallest group	9
2. Interventions		**25**
G	Interventions included in protocol and described	10
H	Pragmatic study	5
I	Co-interventions avoided	5
J	Placebo-controlled	5
3. Effect		**30**
K	Patients blinded	5
L	Outcome measures relevant	10
M	Blinded outcome assessments	10
N	Follow-up period adequate	5
4. Data-presentation and analysis		**10**
O	Intention-to-treat analysis	5
P	Frequencies of most important outcomes presented for each treatment group	5
	TOTAL SCORE	100

Adapted from Koes BW et al. Efficacy of epidural steroid injections for low-back pain and sciatica: A systematic review of randomized clinical trials. *Pain* 1995; 63:279-288 (51).

Table 8. *Methodology for updates to the ACOEM Practice Guidelines, 2nd edition (33).*

Criteria	Rating Description
Randomization	Assessment of the degree that randomization was both reported to have been performed and successfully achieved through analyses of comparisons of variables between the two groups
Treatment Allocation Concealed	Concealment of the allocation scheme from all involved, not just the patient
Baseline Comparability	Measurement of how well the baseline groups are comparable (e.g., age, gender, disease duration, prior treatment)
Patient Blinded	Blinding of the patient/subject to the treatment administered
Provider Blinded	Blinding of the provider to the treatment administered
Assessor Blinded	Blinding of the assessor to the treatment administered
Controlled for Co-interventions	The degree to which the study design controlled for multiple interventions (e.g., a combination of stretching exercises and anti-inflammatory medication or mention of not using other treatments during the study)
Compliance Acceptable	Measurement of the degree of non-compliance
Dropout Rate	Measurement of the dropout rate
Timing of Assessments	Assessment of whether the timing of measurements of effects is the same between treatment groups
Analyzed by Intention to Treat	Ascertainment of whether the study was analyzed with an intent-to-treat analysis

Adapted from the American College of Occupational and Environmental Medicine (ACOEM) Low Back Disorders. In *Occupational Medicine Practice Guidelines: Evaluation and Management of Common Health Problems and Functional Recovery of Workers, Second Edition*. OEM Press, Beverly Farms, 2007 (33).

Results

The results are described below for diagnostic studies followed by therapeutic interventions.

Lumbar Discography

Based on the evidence synthesis by ACOEM, discography, whether performed as a solitary test or when paired with imaging (e.g., magnetic resonance imaging), is moderately not recommended for acute, subacute, chronic low back pain or radicular pain syndromes, with strength of evidence (B) moderate.

The description of the rationale includes Carragee et al's report (88) that estimated a positive predictive value of 50% or below, which means the test is not helpful. The impetus has been that there has not been any evidence for lumbar discography because there are no randomized controlled trials available, even though 7 studies have been incorporated in their analysis, including 2 systematic reviews, one guideline, and 10 other studies (88-98).

Is Randomization Required or Appropriate for Diagnostic Studies?

The ACOEM guidelines have criticized a lack of randomized trials for provocative discography. However, the footnotes of ACOEM's evidence criteria illustrate "for diagnosis and screening, cross-sectional studies using independent gold standards." Further, quality assessment of diagnostic studies always involves observational studies rather than randomized, double-blind trials (47,99-102). Criteria include assessment of spectrum of disease, verification, blinding, patient selection (consecutive or non-consecutive, but not randomized), and data collection - either retrospective or prospective (99). Quality assessment criteria described by the Standards for Reporting of Diagnostic Accuracy (STARD) initiative (100) requires 7 standards, including spectrum composition, analysis of pertinent subgroups, avoidance of workup bias, avoidance of review bias, precision of results for test accuracy, presentation of indeterminate test results, and test reproducibility. Quality assessment by AHRQ criteria for diagnostic studies (47) includes study population, adequate description of test, appropriate reference standard, blinded comparison of test and reference, and avoidance of verification bias (Table 6). Quality assessment by Quality Assessment Studies of Diagnostic Accuracy (QUADAS) criteria for diagnostic studies (101) and STARD checklist (102) do not show any descriptions for randomized trials. Even Carragee et al (103) have not described the requirement of randomization for diagnostic studies. Further review of all Carragee's studies (88,92-96,104,105) illustrates a lack of randomization. Consequently, the recom-

mendation for randomization for diagnostic studies in quality assessment indicates the lack of utilization of evidence-based principles in development of the ACOEM guidelines.

Standardization of Discography Technique and Gold Standard

The technique of discography is standardized by both the International Association for the Study of Pain (IASP) criteria (106) and International Spine Intervention Society (ISIS) (107) and it has been well studied (59,64,108-114). The definition of a positive discogram, per ISIS/IASP standards is pain > 7/10, concordance, pressure ≤ 50 psi a.o, Grade III anular tear, and a painless control disc. In an ideal situation, a gold standard or criterion is obtained by tissue confirmation of the presence or absence of a disease; however, surgical inspection of a degenerated disc cannot determine if discogenic pain is or is not present. Instead of using accepted standards, Carragee et al (115) used a criteria derived from the Walsh et al study (116), with a higher pressure limit of 100 psi a.o.. Carragee et al's studies (112) also used manual pressurization with monitoring of static as opposed to dynamic pressures. Although this method is commonly used, uncontrolled pressurization can produce high intradiscal dynamic pressure which can evoke significant pain in an otherwise non-pathologic disc. Moreover, the ACOEM guideline authors have only utilized all the negative literature available (88,92-96,104,105), and have failed to balance the approach by utilizing the articles which contradicted the described findings (59,64,108-114,117,118).

Inclusion of Scientifically Controversial Studies and Exclusion of Admissible Studies

Carragee et al's (88) report of the low predictive value of discography was based on a study comparing surgical outcomes in the control isthmic spondylolisthesis group versus the discogenic pain group (both with a single level low pressure positive discogram). In the control group, 72% (23/32) of patients met highly effective success criteria as opposed to the 27% (8/30) in the discogenic pain group. They used surgical intervention as the gold standard and compared 2 completely different low back pain populations. It is common knowledge the state-of-the-art surgical interventions for painful single level isthmic spondylolisthesis are superior to those for discogenic pain (88,119-121). In general, outcomes for surgical treatment of chronic axial discogenic low back pain are variable (104,120-122). Carragee et al's outcomes are within the range of expected results. Based on these apparently suboptimal results, opponents state that discography is not a reliable test. Lack of substantial relief from surgery does not mean that discography is inaccurate. Furthermore, contrary to Carragee et al's findings, utilizing pressure-controlled discography, Derby et al (111) reported that precise, prospective categorization of positive discographic diagnoses can predict outcomes from treatment, both surgical and non-surgical, and enhance clinical decision-making.

The ACOEM guidelines selected 2 additional negative studies regarding surgery and discography (89,97). Madan et al's study (97) was a consecutive case series in a private practice. The surgical outcomes for the 43 patients not undergoing discography and the 32 patients undergoing discography prior to surgery were similar; therefore the objective utility of discography was questioned. The description of the discographic technique and operational criteria for a positive response was inadequate and outdated: "a low pressure, low volume injection was performed first to confirm location, and then a high pressure, high volume injection was administered." This data, collected from 1997 to 1999, has many shortcomings: no clear pain-response criteria (i.e. pain > 7/10), no pressure control or criteria, no mention of actual volume injected (current recommendation is ≤ 3.5 mL), no control of speed of injection, and no mention of a control disc. The second study (89) was a retrospective cohort study of the current procedural terminology (CPT) codes of injured workers who underwent lumbar fusion from 1994 to 2001. The authors reported lumbar discography to be an independent predictor of greater re-operation risk. Approximately 13% of patients underwent discography. There is no description of clinical context, indications, technique, or the criteria used for patients undergoing discography. No mention is made of whether or not other commonly recognized pain generators (facet joint/sacroiliac joint) were ruled out first. Surgical techniques were variable, including cages alone, instrumentation alone, cages and instrumentation, and neither. The data state that during this time the use of cages increased from 3.6% in 1994 to 58% in 2001. Use of cages was associated with more post-operative complications than bone-only fusions. Discography patients were statistically more likely to receive cages. Given that we know nothing about how discography was performed in these patients with inclusion of only

13% of the patients, at a time without clear discography standards, discography cannot be adequately evaluated based on poor surgical outcomes during the admittedly unsuccessful surgical "cage rage" era.

Inaccurate Proportion of False-Positive Rates

A series of published studies specifically investigated the potential false-positive rate by performing discography on asymptomatic volunteers (93-96,113,115,116). The Holt study (123) is excluded because it was performed on prisoners, with outdated techniques and noxious, irritating contrast dye. If all the available data (from 1968 to 2008) on asymptomatic volunteers without confounding factors (somatization disorder, chronic pain, or discectomy) is pooled, there are a total of 33 patients and 48 discs (Walsh study (n=10); Carragee study (no chronic pain, no low back pain, n=10) and the Derby study (n=13) (Table 9). The data shows a false-positive rate of 3.0% (1/33) per patient (95% CI, 0%-9%) and 2.1% (1/48) per disc (95% CI, 0%-6%), utilizing both the Carragee criteria and ISIS/IASP standard, even when the provocation stimulus measured by intradiscal pressure is uncontrolled (124).

Based on a critique of use of high and uncontrolled pressures, Carragee et al re-analyzed prior studies according to a low pressure criteria. They (104) reported a rate of low pressure positive disc injections of 25% (17/69 patients) in subjects asymptomatic of significant low back pain illness. This rate was not sta-

Table 9. Pooled table of volunteers asymptomatic of low back pain. †*

Pressure psi a.o.	Pain response NRS 1-10											
		0	1	2	3	4	5	6	7	8	9	10
	100	○† ○† ○† ○†	○									
	90	○†										
	80	○	○	■		■	○†					
	70	○○○		○								
	60	○○○○	○			○	○					
	50	○○○■ ▲▲ ▲	○	■▲	○† ○	○▲	○					
	40	■				○						
	30	○■■	○			○						
	20		○			■					❑	
	10			■								
	0											

*○: 33 discs per Derby et al (113); ▲: 5 discs per Walsh et al (116) study (pressure range 58-72 psi a.o.); ■: 9 discs reported as negative per Carragee et al (94) (no pain, no low back pain group); ❑: case reported as positive per Carragee et al (94). Light and dark cream: Derby et al (111) criteria; dark cream: ISIS/IASP standard (106).

†Grade 2 anular tear (all other patients with grade 3 anular tears)

ISIS = International Spine Intervention Society; IASP =I nternational Association for the Study of Pain; NRS = Numerical rating scale

Adapted from Wolfer L et al. Systematic review of lumbar provocation discography in asymptomatic subjects with a meta-analysis of false-positive rates. *Pain Physician* 2008; 11:513-538 (124).

tistically significantly different from the 27% positive rate (14/52) in their comparison cohort of patients with presumed chronic discogenic pain. This exploratory post-hoc analysis was performed on 5 prior experimental groups (no pain, no low back pain (n=10); chronic pain (n=10); somatization disorder (n=4); post-discectomy (n=20); and mild persistent backache (n=25). Low pressure positive was defined as ≤ 22 psi a.o., which is higher than the standard set by ISIS/IASP of ≤ 15 psi a.o. (107). The individual groups had the following false-positive responses: pain free 0/10, chronic pain 3/10, somatization disorder 2/4, post-discectomy 5/20, and "benign" backache, 7/25 patients.

There were significant shortcomings in Carragee et al's (104) combination of these studies and conclusions. Each subgroup merits individual scrutiny (Table

Table 10. *Summary of false-positive rates (%) per patient and per disc for experimental studies in subjects asymptomatic of low back pain.*†*

STUDY	Walsh et al (116)/ Carragee et al (94)		Derby et al (111)		ISIS/IASP (106)						Low pressure ≤ 22 psi a.o (Carragee)		Low pressure ≤ 15 psi a.o. (Derby)	
					a		b		c					
	%FP /pt	%FP /disc	%FP /pt	%FP /disc	%FP /pt	%FP /disc	%FP /pt	%FP /disc	%FP /pt	%FP /disc	%FP /pt	%FP /disc	%FP /pt	%FP /disc
Walsh et al (116): Asymptomatic volunteers (95% CI)	0 (-)	0 (-)	0 (-)	0 (-)	0 (-)	0 (-)	0 (-)	0 (-)	0 (-)	0 (-)	0 (-)	0 (-)	0 (-)	0 (-)
Carragee et al (115) Iliac crest (95% CI)	50 (5 – 95%)	28.6 (2 – 56%)	37.5 (0 – 81%)	21.4 (0 – 46%)	12.5 (0 – 42%)	7.1 (0 – 23%)	12.5 (0 – 42%)	7.1 (0 – 23%)	12.5 (0 – 42%)	7.1 (0 – 23%)	25 (0 – 64%)	14.3 (0 – 35%)	12.5 (0 – 42%)	7.1 (0 – 23%)
Carragee et al (94): pain-free (cs-good) (95% CI)	10 (0 – 33%)	10 (0 – 33%)	10 (0 – 33%)	10 (0 – 33%)	10 (0 – 33%)	10 (0 – 33%)	10 (0 – 33%)	10 (0 – 33%)	10 (0 – 33%)	10 (0 – 33%)	0 (-)	0 (-)	0 (-)	0 (-)
Carragee et al (94): chronic pain (cs-failed) (95% CI)	40 (3 – 77%)	58.3 (26 – 91%)	30 (0 – 65%)	33.3 (2 – 65%)	20 (0 – 50%)	16.7 (0 – 41%)	10 (0 – 33%)	8.3 (0 – 27%)	0 (-)	0 (-)	30 (0 – 65%)	25 (0 – 54%)	10 (0 – 33%)	8.3 (0 – 27%)
Carragee et al (96): Somatization disorder (95% CI)	75 (0 – 100%)	44.4 (4 – 85%)	50 (0 – 100%)	22.2 (0 – 56%)	50 (0 – 100%)	22.2 (0 – 56%)	50 (0 – 100%)	22.2 (0 – 56%)	50 (0 – 100%)	22.2 (0 – 56%)	50 (0 – 100%)	22.2 (0 – 56%)	25 (0 – 100%)	11.1 (0 – 37%)
Derby et al (113): Asymptomatic volunteers (95% CI)	0 (-)	0 (-)	0 (-)	0 (-)	0 (-)	0 (-)	0 (-)	0 (-)	0 (-)	0 (-)	0 (-)	0 (-)	0 (-)	0 (-)
Carragee et al: (93) mild backache (95% CI)	36 (16 – 56%)	37.5 (20 – 55%)	36 (16 – 56%)	31.3 (14 – 48%)	20 (3 – 37%)	15.6 (2 – 29%)	20 (3 – 37%)	15.6 (2 – 29%)	16 (1 – 31%)	12.5 (0.4 – 25%)	28 (9 – 47%)	21.9 (7 – 37%)	28 (9 – 47%)	21.9 (7 – 37%)
Carragee et al (95): Post-discectomy (95 % CI)	35 (12 – 58%)	24.2 (9 – 40%)	35 (12 – 58%)	24.2 (9 – 40%)	25 (4 – 46%)	15.2 (2 – 28%)	25 (4 – 46%)	15.2 (2 – 28%)	15 (0 – 32%)	9.1 (0 – 19%)	25 (4 – 46%)	18.2 (4 – 32%)	25 (4 – 46%)	15.2 (2 – 28%)

*ISIS = International Spine Intervention Society; IASP = International Association for the Study of Pain; a = no control disc; b = control disc ≤ 6/10; c = painless control disc; FP = false positive; pt = patient; cs-good: cervical spine surgery, good outcome; cs-failed: cervical spine surgery, poorest outcome; CI : Confidence Intervals

† Holt (123) and Massie WK, Stevens DB. A critical evaluation of discography. *J Bone Joint Surg Am* 1967; 49A:1243-1244.studies are not included as pain and pressure were not reported in the published study.

Adapted from Wolfer L et al. Systematic review of lumbar provocation discography in asymptomatic subjects with a meta-analysis of false-positive rates. *Pain Physician* 2008;11:513-538 (124).

10). The pain-free group had a 0% false-positive rate. The low pressure positive chronic pain group included 3/10 chronic pain patients who were disabled volunteers with failed cervical fusions, on regular medications (including opioids), with markedly abnormal psychometric scores, and, with active worker's compensation litigation. In the latter group, with high pressure provocation (pressure ≤ 100 psi a.o.), Carragee et al (104) reported a false-positive rate of 40%, however, because of the small numbers, the 95% confidence level was broad, ranging from 10% to 70%. If one uses accepted standards from ISIS/IASP (106,107) of ≤ 15 psi a.o., the false-positive rate is 10% per patient (1/10) (95% CI, 0% – 33%) and 8.3% per disc (1/12) (95% CI, 0% – 27%) (124). Furthermore, in the analysis, Carragee et al (104) included 2 patients with somatization disorder who could arguably be removed from consideration given the small sample size of 4 patients and the large confidence intervals by both the Carragee et al and ISIS/IASP criteria, respectively (75% false-positive rate per patient (95% CI, 0% – 100%) versus 50% (95% CI, 0% – 100%) (Table 10).

Carragee et al (95) also included 5 patients in whom a prior discectomy had been performed at the index level. In this study, they reported a 40% (8/20) false-positive rate. However, using the ISIS/IASP standards, the false-positive rate is 15% (3/20) per patient and 9.1% (3/33) per disc (Table 10) (124). Asymptomatic post-discectomy patients who have a history of severe low back pain requiring surgery and surgically altered disc anatomy should be thoughtfully evaluated by the expert discographer. To lessen the false-positive rate, strict operational criteria, with monitoring of dynamic and static pressures and control of injection speed, may be appropriate in this patient population (112).

Lastly, in their study of low pressure positive discography, Carragee et al (93) included 7 low-pressure positive backache patients, with a history of chronic persistent back pain that on a daily basis was rated at 2 to 4/10 intensity. To be included in the original backache study, the patients answered yes to the following question: "I have low back pain every day or I have back pain almost every day." In the study of chronic low back pain patients, the 36% (9/25) positive responses are not false-positives but an affirmation that the patient's back pain is due to a painful intervertebral disc. The argument that these positive responses represent false-positive responses is not supportable. In fact, the figure of 36% is almost identical to the 39% prevalence of internal disc disruption reported using discographic diagnoses by Schwarzer et al (125). Furthermore, Manchikanti et al (126) evaluated the relative contributions of various structures in chronic low back pain and showed discogenic pain to be present in 26% of the patients. Thus, Carragee et al's subjects may have been in a more quiescent phase of their illness; moreover, discography does not determine the clinical significance of a patient's perceived suffering and disability related to chronic low back pain. These 7 patients should be removed from the analysis. In summary, Carragee et al's (104) post-hoc analysis of select populations with low pressure positive discograms does not hold up to closer scrutiny and the conclusion that the false-positive rate of low pressure discography in asymptomatic subjects is unsupportable.

Carragee et al (115) also studied patients with residual pain after iliac crest bone graft harvesting. They reported that 50% of patients (4/8) experienced a positive response with concordant pain. Per disc, Carragee et al's false-positive rate was 28.6% (4/14). Using the ISIS/IASP standards (106,107), the false-positive rate drops to 12.5% (1/8) per patient and 7.1% (1/14) per disc (Table 10) (124). Carragee et al's results demonstrate the importance of ruling out specific sources of pain prior to discography (including facet or sacroiliac pain), as their studies show that there may be segmental overlap in innervation of deep somatic structures. Lastly, discography should always be performed on the asymptomatic or least symptomatic side to avoid false-positive responses. Carragee et al's studies did not state the side on which discography was performed.

In individuals without specific confounding factors, the current evidence shows that the likelihood of a false-positive response is very low (124), however, the argument made by Carragee et al (94) is that these subjects do not represent the population for which discography is being performed. However, no evidence to support this contention was presented. Based on their data from 10 patients with chronic cervical pain, they found a false-positive rate of 40%, suggesting that discography is not an accurate or reliable test in patients with chronic pain (94). In fact, when the hypothesis that patients with chromic back pain will over report pain during discography compared to volunteers without chronic pain was directly studied (108), it was found that patients with chronic low back pain responded the same as asymptomatic volunteer subjects. That is, the pain responses of 52.3% of Grade III discs in chronic low back pain patients with negative discograms were

not statistically significant from 58.2% of Grade III discs in asymptomatic volunteers at 15, 30, 50 psi or maximal pressure above opening (for example, at 50 psi, the negative patient disc Numerical Rating Score (NRS) score was 1.1/10 versus 1.6/10 for the asymptomatic controls). There was however, a statistically and clinically significant difference between negative patient discs and those that meet the criteria for a positive response (i.e., at 50 psi, NRS was 8.7/10, $P \leq 0.001$). Subjects with chronic low back pain could clearly distinguish between a positive and negative discogram. Thus the current evidence shows that the very low false-positive rate obtained by all prior studies, including Carragee et al's (94) study on asymptomatic volunteers without chronic pain, are applicable to a majority of patients presenting for lumbar discography.

Shin et al (118) also evaluated the diagnostic relevance of pressure-controlled discography, showing that pain responses were well correlated with intradiscal pressure, but not with the amount of injected volume. Further, among the discs with Grade IV and V tears, 74% tested with a positive response. Consequently, they concluded that pressure-controlled discography was useful to diagnose discogenic pain, and an excellent guide in decision-making for spinal operations. Simmons et al (117), in a comparison study of provocation discography with magnetic resonance imaging (MRI), concluded that MRI is a static test and discography is the only available dynamic test for disc evaluation that can determine abnormal discs with symptom reproduction. Carragee et al (105), with all the negative studies in limited populations with repeat publications, also concluded that the development of serious low back pain disability in a cohort of subjects was strongly predicted by baseline psychosocial variables, whereas structural variables on both MRI and discography testing at baseline had only weak association with back pain episodes and no association with disability or future medical care. In contrast, Manchikanti et al (114) showed no significant difference in the results of provocation discography in low back pain patients, with or without somatization disorder, in a prospective evaluation. Further, Manchikanti et al (127) also showed a similar response to epidural injections in discogram positive and negative patients.

Finally, per Wolfer et al (124), one can combine all the data from studies of lumbar discography in subjects asymptomatic of low back pain into a single table (Table 10) and obtain an acceptably low false-positive rate per patient and per disc (all discs ≥ grade 2 anular tear). This combined analysis excludes symptomatic backache patients and somatization disorder patients (n=2) with an incomplete data set. Using the ISIS/IASP standard, the combined analysis of 75 patients and 116 discs obtains a false-positive rate of 9.3% (95 CI 3 – 16%) per patient and 6.0% (95 CI 2 – 10%) per disc (Table 10). Contrary to recent negative publications, this systematic review and meta-analysis of the literature on provocation discography in asymptomatic subjects shows lumbar discography to have an acceptably low false-positive rate.

Discography and Interobserver Agreement

The ACOEM guidelines also claim that there is no interobserver agreement in performing discography. However, there is a high inter- and intraobserver agreement in assessing discography morphology (128,129).

Accuracy of Lumbar Discography

The accuracy of discography as an imaging test is high for the diagnosis of disc degeneration. The face validity of discography has been established by injecting small volumes of contrast into the disc and determining concordant pain, with spread of the contrast medium in the posteroanterior and lateral radiographs and/or computed tomography (CT). The construct validity of the discogram is important to avoid a false-positive result and obtain a true-positive response. Consequently, for a response to be considered positive, concordant pain must be reproduced; and for the test to be valid, there must be at least one disc (preferably 2) that does not elicit pain upon injection, thereby serving as a control disc (59,64,106,107).

In contrast to the claims of the ACOEM guidelines, the sensitivity and specificity of intervertebral disc morphology are 81% and 64% respectively. A recent meta-analysis of provocation discography in asymptomatic subjects obtained a specificity of 94% (95% CI, 89 – 98%) and a false-positive rate of 6% (124). Discography has been also compared with myelography, CT, MRI, and the results of surgical and conservative management, and the special advantages of discography over MRI and other tests have been identified.

Reassessment

A reassessment of the studies utilized in the evaluation by the ACOEM guidelines was carried out with

supplementation of multiple other studies available in the literature.

Methodologic Quality Assessment

Methodologic quality assessment criteria are listed in Table 11. Table 12 illustrates descriptive characteristics of diagnostic studies of lumbar discography. Among all the available 16 studies, only one study was utilized by the ACOEM guidelines and a score was not available by ACOEM. However, the reassessment score using AHRQ criteria was 45 (88). Thus, multiple studies (4 of 7) by Carragee et al scored below 50 (88,93,95,104). However, the other 3 studies by Carragee et al (94,96,115) scored above 50. In contrast, all the other studies scored above 50 ranging from 65 to 80 (108,110,111,113,114,116,118,125,126).

Carragee et al also have used fusion as the gold standard, which is against their own criticism of other studies (88,103). Carragee et al (130,131) repeatedly criticized controlled diagnostic blocks which have used relief of pain as the gold standard.

Prevalence of Lumbar Discogenic Pain

Prevalence of pain due to internal disc disruption has been reported in 39% of patients suffering with chronic low back pain (125) and primary discogenic pain is present in 26% of patients suffering with chronic low back pain in the United States (Table 13) (126).

Level of Evidence

Reassessment of the evidence provided by the ACOEM guidelines shows that all the studies utilized by the ACOEM guidelines and others available are non-randomized based on the appropriate criteria (47,99-102). The discography technique has been standardized based on the criteria of IASP (106). Extensive

Table 11. *Methodologic quality evaluation and scoring of lumbar discography studies.*

STUDY	1 Study Population (30)	2 Adequate Description of Test (15)	3 Appropriate Reference Standard (20)	4 Blinded Comparison of Test (20)	5 Avoidance of Verification Bias (15)	TOTAL (100)
Carragee et al 2006 (88)*	15	15	0	0	15	45
Carragee et al 2006 (104)	15	15	0	0	15	45
Carragee et al 2002 (93)	15	15	10	0	0	40
Carragee et al 2000 (96)	30	15	20	0	0	65
Carragee et al 2000 (95)	30	15	0	0	0	45
Carragee et al 2000 (94)	20	15	20	0	0	55
Carragee et al 1999 (115)	10	15	20	0	15	60
Derby et al 1999 (111)	30	15	20	0	0	65
Derby et al 2005 (108)	30	15	20	0	15	80
Derby et al 2005 (110)	30	15	20	0	15	80
Derby et al 2005 (113)	30	15	20	0	15	80
Shin et al 2006 (118)	30	15	20	0	15	80
Walsh et al 1990 (116)	30	15	10	0	15	70
Schwarzer et al 1995 (125)	30	15	20	0	15	80
Manchikanti et al 2001 (114)	30	15	20	0	15	80
Manchikanti et al 2001 (126)	30	15	20	0	15	80

* Indicates use in ACOEM guidelines; ( ) weighted item score

Methodological criteria and scoring adapted from West S et al. Systems to Rate the Strength of Scientific Evidence, Evidence Report, Technology Assessment No. 47. AHRQ Publication No. 02-E016 (47).

Table 12. *Descriptive characteristics of diagnostic studies of a lumbar discography.*

Study	Methodological Assessment		Participants	Conclusions	
	ACOEM Score	Reassessment Score		Authors' Conclusion	Review Conclusion
Carragee et al 2006 (88)	NA	45	Discogenic pain=32 Spondylolisthesis group=30	Positive discography not highly predictive of success of fusion	Fusion is not a proven treatment for discogenic pain
Carragee et al 2006 (104)	NUA	45	Asymptomatic of significant low back pain illness=69 Clinical low back pain group=52	25% positive discograms in patients without significant low back pain illness	Very broad CI levels with poor inclusion criteria (e.g. somatization disorder patients and symptomatic chronic low back pain patients)
Carragee et al 2002 (93)	NUA	40	Mild CLBP=25 CLBP=52	36% positive challenged specificity	Similar to 26%-39% in controlled trials (125,126)
Carragee et al 2000 (96)	NUA	65	26 asymptomatic patients with (15) or without (11) psychological abnormalities	Significant back pain in patients with emotional problems	Asymptomatic patients do not receive discography
Carragee et al 2000 (95)	NUA	45	Asymptomatic postsurgery=20 Intractable pain-laminectomy=27	High false-positive rate after limited lumbar discectomy	Poor operational criteria
Carragee et al 2000 (94)	NUA	55	26 individuals without low back pain, with 10 pain free, 10 chronic neck pain, 6 primary somatization disorder	Significant positive responses in patients with chronic neck pain (40%), somatization disorder (SD) (83%)	Inappropriate conclusions With strict operational criteria and standards, false-positive rate can be reduced to 0% in chronic neck pain patients. SD patients with small sample size, broad CI, incomplete data set in 2/6 patients
Carragee et al 1999 (115)	NUA	70	8 asymptomatic subjects who had undergone posterior iliac crest bone graft harvesting, and who, by pain drawing and psychometric testing, appeared reliable discography candidates	Authors questioned the ability of a patient to separate spinal from non-spinal sources of pain on discography and concluded that a response of concordant pain on discography may be less meaningful than often assumed	Asymptomatic patients do not receive discography. Consequently, the usual gluteal area pain may not be reproduced. Re-analysis of the data showed false-positive rate of 12.5% per patient or 7.1% per disc in contrast to the false-positive rate reported by Carragee et al of 50% per patient and 28.6% per disc (124)
Derby et al 1999 (111)	NUA	65	96 patients who had lumbar discography and subsequently underwent interbody fusion alone, combined fusion, intertransverse fusion, or no surgery were studied.	Patients with low pressure positive ≤ 15 psi a.o. ("chemically sensitive") discs appear to achieve significantly better long-term outcomes with interbody/ combined fusion than with intertransverse fusion. Patients without disc surgery have the least favorable outcome.	Review concurs with authors' conclusions

Table 12 (cont.). *Descriptive characteristics of diagnostic studies of a lumbar discography.*

Study	Methodological Assessment		Participants	Conclusions	
	ACOEM Score	Reassessment Score		Authors' Conclusion	Review Conclusion
Derby et al 2005 (108)	NUA	80	16 healthy volunteers without current back pain and 90 patients with chronic low back pain	Pain tolerance was significantly lower in patients relative to symptomatic subjects. Negative patient discs and asymptomatic subject discs showed similar characteristics. Pressure-controlled manometric discography using strict criteria may distinguish symptomatic discs among morphologically abnormal discs with grade III annular tears in patients with suspected chronic discogenic low back pain.	The study results indicate validity of discography
Derby et al 2005 (110)	NUA	80	86 patients suspected of discogenic pain	Annular disruption directly correlates with discography findings for asymptomatic disc when pressure-controlled manometric techniques with strict criteria are used. Annular disruption reaching the outer third of the annulus fibrosus is a key factor in pain generation. Morphologic findings such as annular disruptions extending into or beyond the outer annulus may increase discography specificity.	Authors demonstrated relation between annular disruption and pressure-controlled discography.
Derby et al 2005 (113)	NUA	80	4 lay persons and 9 physicians underwent lumbar discography, with manometry	Lumbar discs in asymptomatic volunteers can be made painful, but as a rule, the pain is mild and requires high pressures of injection. If attention is paid to pressure of injection and intensity of response, operational criteria can be defined that provide lumbar discography with a potential false-positive rate of 0 or less than 10%.	This study provides a potential false-positive rate of less than 10% when lumbar provocation discography is performed utilizing appropriate criteria.
Shin et al 2006 (118)	NUA	80	21 patients with clinically suspected discogenic low back pain who underwent pressure-controlled discography.	Pressure-controlled discography was useful to diagnose discogenic pain and excellent guide in decision-making for spinal operations.	Pressure-controlled discography was useful to diagnose discogenic pain.
Walsh et al 1990 (116)	NUA	70	7 patients with low back pain and 10 volunteers without history of low back pain underwent discography at 3 levels.	5 patients had positive discograms on the basis of the study criteria, leading to the conclusion that with current techniques and in conjunction with standardized methods for assessment of pain, lumbar discography is a highly reliable and specific diagnostic test. Authors also concluded that discography is not the best diagnostic test for all patients who have low back pain.	This study provided a false-positive rate of 0% in asymptomatic subjects. The results indicate validity of discography.

Table 12 (cont.). *Descriptive characteristics of diagnostic studies of a lumbar discography.*

Study	Methodological Assessment		Participants	Conclusions	
	ACOEM Score	Reassessment Score		Authors' Conclusion	Review Conclusion
Schwarzer et al 1995 (125)	NUA	80	92 consecutive patients with low back pain referred for discography in 1992 were studied	A diagnosis of internal disc disruption can be made in a significant proportion of patients with chronic low back pain, but no conventional clinical test can discriminate patients with internal disc disruption from patients with other conditions. They established prevalence of 39% of the patients fully satisfying the criteria of internal disc disruption.	The first trial providing the prevalence and clinical features of internal disc disruption in patients with chronic low back pain.
Manchikanti et al 2001 (114)	NUA	80	50 randomly assigned patients with 25 patients in Group I without somatization disorder and 25 patients in Group II with diagnosis of somatization disorder. In addition, depression, generalized anxiety disorder, and combinations thereof were also evaluated.	Provocative discography provides similar results in patients with or without somatization, with or without depression, with somatization but with or without depression or with other combinations of the psychological triad of somatization disorder, depression, and generalized anxiety disorder.	Provocative discography provides similar results in patients with or without somatization.
Manchikanti et al 2001 (126)	NUA	80	120 patients with a chief complaint of low back pain were evaluated with precision diagnostic injections, which included medial branch blocks, provocation discography, and sacroiliac joint injections. Initially, all patients underwent diagnostic facet joint nerve blocks. Of these, 72 patients negative for facet joint pain underwent discography.	Discogenic pain was seen in 26% of the patients from the total sample of 120 patients. However, after the facet joint pain was eliminated by medial branch blocks, the prevalence was 43%. No attempt was made to correlate with internal disc disruption.	This study provides a prevalence rate of discogenic pain, with or without internal disc disruption.

Table 13. *Data of prevalence of lumbar discogenic pain utilizing IASP criteria.*

Study	Methodological Quality Scoring		Participants	Prevalence
	ACOEM Score x 9.1	Reassessment Score		
Schwarzer et al 1995 (125)	NUA	80	92 consecutive patients with chronic low back pain and no history of previous lumbar surgery referred for discography	The diagnostic criteria for internal disc disruption were fully satisfied in 39% of the patients, most commonly at L5/S1 and L4/5.
Manchikanti et al 2001 (126)	NUA	80	From a group of 120 patients with low back pain, 72 patients negative for facet joint pain underwent discography.	The prevalence of discogenic pain was established in 26% of total patient sample and 43% of patients negative for facet joint pain.

NUA=not utilized in analysis by authors of ACOEM guidelines

review of all the available studies showed the validity of lumbar provocation discography when performed as per IASP criteria.

Outdated quality of evidence criteria utilized by ACOEM (33) adapted and modified from AHCPR (Table 5) (23), provides the evidence A — strong evidence-base: for diagnosis and screening, cross-sectional studies using independent gold standards. If pain relief and contiguous negative discs to avoid false-positives is considered as gold standard, the evidence is strong. There is no other level of evidence for diagnostic interventions based on ACOEM criteria. Further, all the criteria utilized by ACOEM and Carragee et al shows widespread confidence intervals. In addition, in this analysis, only the studies meeting the inclusion criteria with methodological quality of 50 or above are included.

Based on the AHRQ USPSTF criteria (Table 3) (21), the evidence is Level I, strong, with inclusion of the studies with quality criteria of above 50.

However, the inclusion of lower quality studies does not change the level of evidence.

Prevalence

Based on the available studies performed utilizing IASP criteria (125,126), the prevalence of internal disc disruption is 39%, and discogenic pain is 26% in patients with chronic low back pain in patients without disc herniation or radicular symptoms.

Recommendations

Based on grading recommendations by Guyatt et al (19) the grade of recommendation is 1A strong recommendation with high quality evidence, with benefits clearly outweighing risks and burdens, with strong evidence from observational studies (appropriate for diagnostic studies), resulting in a strong recommendation which can apply to most patients in most circumstances without reservation.

The recommendation has been downgraded from 1A to 1B or 1C based on the controversy and negative recommendations by Carragee et al.

Diagnostic Facet Joint Interventions

The ACOEM guidelines (33,34) describe intraarticular injections and facet joint nerve blocks for diagnosis. The authors of the guidelines used 2 old (15 years old) studies (132,133) and 3 narrative reviews (134-136). They also described an indication for diagnostic intraarticular injections of lumbar segmental rigidity, which is not an acceptable indication in interventional pain management (137). They concluded that for chronic low back pain, there was no recommendation due to insufficient evidence. Not describing the role of cervical and thoracic diagnostic facet joint nerve blocks separately, the guidelines (34) concluded that cervical radiofrequency neurotomy is ineffective based on the rate of false-positive facet joint injections in the cervical spine, estimated at 27% (138). Further, the ACOEM guidelines (34) contend that there is a lack of clarity about the pain generators and the potential for multiple pain generators is present in a given patient. Additional comments made in the ACOEM guidelines include that the prevalence of this disorder is unclear and likely varies widely, particularly from primary to tertiary patient care settings and has been estimated at 25% to 50% (139,140).

The study by Jackson (132) published in 1992 is not only 16 years old, but flawed. El-Khoury and Renfrew (133) explained that intraarticular blocks are sometimes combined and provide a combined diagnostic and therapeutic intervention. The 3 reviews (134-136) were narratives. Even then, they have been grossly misquoted and misrepresented.

Inappropriate Utilization of Scientifically Inadmissible Studies

The authors of the ACOEM guidelines, as they did for provocation discography, call for randomized controlled trials for evidence assessment for diagnostic facet joint injections, and then based their recommendations on 4 flawed randomized controlled trials (137,141-143). However, quality assessment of diagnostic studies should not involve randomized trials. Rather, it involves consecutive or non-consecutive allocation and observational studies (47,99-102). The lack of appropriate evidence synthesis by ACOEM is demonstrated by reviewing the 4 randomized controlled trials they based their recommendations on. Mayer et al (137) published a randomized clinical trial of treatment for lumbar "segmental rigidity." They evaluated facet joint injection plus exercise versus exercise alone for 70 chronic low back pain patients thought to have segmental rigidity. As per the ACOEM guidelines, the issue of relevance was that 5 of 29 patients (17.2%) met the criteria for facet syndrome involving an 80% reduction in pain 1 to 2 hours after injection, when all levels had been injected bilaterally for suspected segmental rigidity. In this evaluation, patient selection was inappropriate, and the blocks were performed in-

accurately thus raising numerous questions. At best, this evaluation indicates that in patients with so called segmental rigidity, approximately 17.2% may have pain of facet joint origin, which is in the reported range of prevalence of 15% to 45%. As a result, this study has no diagnostic relevance.

The second study, by Lilius et al (142), was excluded in the evidence synthesis for its low quality (1). The third study involves Marks et al (141) comparing facet joint injections with facet joint nerve blocks under fluoroscopy for therapeutic purposes in chronic low back pain. This study used high volumes of local anesthetic and steroids both for intraarticular injections and medial branch blocks using poor selection criteria and inappropriate monitoring. Finally, the study by Birkenmaier et al (143) compared medial branch blocks with pericapsular blocks among 26 patients thought to have facet joint pain prior to cryodenervation. Even then, the authors of this study concluded that uncontrolled medial branch blocks are superior to pericapsular blocks at selecting patients for facet joint cryodenervation. The authors also concluded that if serial controlled blocks cannot be used, lumbar facet joint pain remains a diagnostic dilemma. While the inclusion of the study shows irrelevance and also a lack of appropriate evaluation by the authors of the ACOEM guidelines, it also indicates that the authors have not taken into consideration any type of positive evidence from the included studies.

Rationale for Diagnostic Facet Joint Nerve Blocks

The rationale for diagnostic blocks of the facet or zygapophysial joint, anesthetizing the joint by injection of local anesthetic intraarticularly or on the medial branches of the dorsal rami that innervate the target joint, is based on the belief that one must test to determine whether a particular joint is the source of the pain. However, valid information is only obtained by performing controlled blocks, either in the form of placebo injections of normal saline or comparative local anesthetic blocks in which, on 2 separate occasions, the same joint is anesthetized using local anesthetics with different durations of action.

The rationale for using facet joint blocks for diagnosis is based on the fact that facet joints are capable of causing pain and they have a nerve supply (144-155). Neuroanatomic studies have demonstrated free and encapsulated nerve endings in facet joints as well as nerves containing substance P and calcitonin gene-related peptide (156-169). Further, spinal facet joints have been shown to be a source of pain in the neck and referred pain in the head and upper extremities (139,170-174); upper back, mid back, and referred pain in the chest wall (175,176); as well as the low back and referred pain in the lower extremity (177-182). Based on controlled diagnostic blocks of facet joints, in accordance with criteria established by the IASP (106), facet joints have been implicated as responsible for spinal pain in 15% to 45% of patients with low back pain (126,183-194); 36% to 67% of patients with neck pain (140,183,185,193-199); and 34% to 48% of patients with thoracic pain (183,185,200).

Reassessment

A reassessment of all the studies utilized in the evaluation by the ACOEM guidelines was performed. Further, it was supplemented by the appropriate addition of multiple other studies available in the literature.

Methodologic Quality Assessment

Methodologic quality assessment of the studies performed for the diagnosis of facet joint pain in the cervical, thoracic, and lumbar regions is illustrated in Table 14. A total of 19 studies were included with all of them meeting inclusion criteria with scores ranging from 65 to 80. None of these were used in the ACOEM guideline development. Instead, they inaccurately utilized studies which have failed to meet the inclusion criteria for methodologic quality assessment (132,133,137).

Results

Results in Tables 15 to 17 illustrate the false-positive rates and prevalence of facet joint pain of the spine. Zygapophysial or facet joints have been shown to be responsible for spinal pain in 15% to 45% of patients with low back pain (126,183-194), 36% to 67% of the patients with neck pain (140,183,185,194-199), and 34% to 48% of patients with thoracic pain (183,185,200). False-positive rates ranged from 17% to 50% in the lumbar spine (126,183,185,189-194,205), 27% to 63% in the cervical spine (138,183,185,193-195,197), and 42% to 58% in the thoracic spine (183,185,200).

Validity of Diagnostic Facet Joint Blocks

Controlled diagnostic blocks with 2 local anesthetics or placebo-controlled are the only means

Table 14. *Methodologic quality assessment and scoring of diagnostic facet joint nerve block studies.*

STUDY	1 Study Population (30)	2 Adequate Description of Test (15)	3 Appropriate Reference Standard (20)		4 Blinded Comparison of Test (20)		5 Avoidance of Verification Bias (15)	TOTAL (100)
Barnsley et al 1995 (196)	30	15	10	10	__	__	15	80
Barnsley et al 1993 (138)	30	15	10	10	__	__	15	80
Lord et al 1996 (140)	30	15	10	10	__	__	15	80
Manchikanti et al 2002 (194)	30	15	10	10	__	__	15	80
Manchikanti et al 2002 (197)	30	15	10	10	__	__	15	80
Manchikanti et al 2004 (185)	30	15	10	10	__	__	15	80
Manchikanti et al 2002 (200)	30	15	10	10	__	__	15	80
Manchukonda et al 2007 (183)	30	15	10	10	__	__	5	70
Manchikanti et al 2008 (195)	30	15	10	10	__	__	5	70
Speldewinde et al 2001 (198)	30	15	10	10	__	__	__	65
Yin and Bogduk 2008 (199)	30	15	10	10	__	__	__	65
Schwarzer et al 1994 (186,205)	30	15	10	10	__	__	15	80
Schwarzer et al 1995 (188)	30	15	10	10	__	__	15	80
Manchikanti et al 1999 (190)	30	15	10	10	__	__	15	80
Manchikanti et al 2000 (191)	30	15	10	10	__	__	15	80
Manchikanti et al 2000 (189)	30	15	10	10	__	__	15	80
Manchikanti et al 2001 (126)	30	15	10	10	__	__	15	80
Manchikanti et al 2003 (192)	30	15	10	10	__	__	15	80
Manchikanti et al 2007 (184)	30	15	10	10	__	__	15	80

( ) weighted item score

Methodological criteria and scoring adapted from West S et al. Systems to Rate the Strength of Scientific Evidence, Evidence Report, Technology Assessment No. 47. AHRQ Publication No. 02-E016 (47).

of confirming the diagnosis of facet joint pain. The face validity of medial branch blocks has been established by injecting small volumes of local anesthetic and contrast material onto the target points for these structures and by determining the spread of contrast medium in posteroanterior and lateral radiographs (55,62,63). Construct validity of facet joint blocks is important to eliminate the placebo effect as a source of confounding results and to secure true-positive results (55,62,63,138,183-185,189-195,201-205). In addition, the hypothesis that testing a patient first with lidocaine and subsequently with bupivacaine provides a means of identifying that the placebo response has been tested and proven (202-204,206,207).

There are no specific markers to diagnose facet joint pain (1). Conventional clinical and radiologic techniques are unreliable in diagnosing facet or zygapophysial joint pain, and various patterns of referred pain described for facet joints in the spine are similar to other structures, such as discs. In addition, most maneuvers used in physical examination are likely to stress several structures simultaneously, thus failing to provide any reasonable diagnostic criteria. The evidence thus far on physical examination and diagnosis has been

Table 15. *Data of prevalence and false-positive rates in cervical region with controlled diagnostic blocks.*

Study	Methodological Quality Scoring (AHRQ)	Participants	Prevalence	False-Positive Rate
Barnsley et al 1995 (196)	80	50	54% (95% CI, 40%–68%)	NA
Barnsley et al 1993 (138)	80	55	NA	27% (95% CI, 15%–38%)
Lord et al 1996 (140)	80	68	60% (95% CI, 46%–73%)	NA
Manchikanti et al 2002 (194)	80	120	67% (95% CI, 58%–75%)	63% (95% CI, 48%–78%)
Manchikanti et al 2002 (197)	80	106	60% (95% CI, 50%–70%)	40% (95% CI, 25%–56%)
Manchikanti et al 2004 (185)	80	255	55% (95% CI, 49%–61%)	63% (95% CI, 54%–72%)
Manchukonda et al 2007 (183)	70	251	39% (95% CI, 32%–45%)	45% (95% CI, 37%–52%)
Speldewinde et al 2001 (198)	65	97	36% (95% CI, 27%–45%)	NA
Manchikanti et al 2008 (195)	80	251	Nonsurgery 39% (95% CI, 33%–46%) Postsurgery 36% (95% CI, 22%–51%)	Nonsurgery 43% (95% CI, 35%–52%) Postsurgery 50% (95% CI, 32%–68%)
Yin and Bogduk 2008 (199)	65	84	55%	NA

NA = not available; AHRQ = Agency for Healthcare Research and Quality
Adapted and modified from Boswell MV et al. Interventional techniques: Evidence-based practice guidelines in the management of chronic spinal pain. *Pain Physician* 2007; 10:7-111 (1).

Table 16. *Data of prevalence with controlled diagnostic blocks and false-positive rates in lumbar region.*

Study	Methodological Quality Scoring (AHRQ)	Participants	Prevalence	False–Positive Rate
Schwarzer et al 1994 (186)	80	176	15% (95% CI, 10%–20%)	NA
Schwarzer et al 1994 (205)	80	176	15%	38% (95% CI, 30%–46%)
Schwarzer et al 1995 (188)	80	63	40% (95% CI, 27%–53%)	NA
Manchikanti et al 1999 (190)	80	120	45% (95% CI, 36%–54%)	41% (95% CI, 29%–53%)
Manchikanti et al 2000 (191)	80	200	42% (95% CI, 35%–49%)	37% (95% CI, 28%–46%)
Manchikanti et al 2000 (189)	80	180	Average 36% I: 38% (CI, 26%–50%) II: 32% (CI, 20%–44%) III: 38% (CI, 26%–50%)	Average 25% I: 22% (CI, 9%–35%) II: 27% (CI, 13%–41%) III: 27% (CI, 13%–41%)
Manchikanti et al 2001 (126)	80	120	40% (95% CI, 31%– 49%)	47% (95% CI, 35%–59%)
Manchikanti et al 2002 (194)	80	120	40% (95% CI, 31%–49%)	30% (95% CI, 20%–40%)
Manchikanti et al 2003 (192)	80	300	I: 21% (95% CI, 14%–27%) II : 41%(95% CI, 33%–49%)	I: 17% (95% CI 10%–24%) II : 27% (95% CI, 18%–36%)
Manchikanti et al 2004 (185)	80	397	31% (95% CI, 27%–36%)	27% (95% CI, 22%–32%)
Manchukonda et al 2007 (183)	70	303	27% (95% CI, 22%–33%)	45% (95% CI, 36%–53%)
Manchikanti et al 2007 (184)	80	117	16% (95% CI, 9%–23%)	49% (95% CI, 39%–59%)

NA = not available
Adapted and modified from Boswell MV et al. Interventional techniques: Evidence-based practice guidelines in the management of chronic spinal pain. *Pain Physician* 2007; 10:7-111 (1).

Table 17. *Data of prevalence with controlled diagnostic blocks and false-positive rates in thoracic region.*

Study	Methodological Quality Scoring (AHRQ)	Participants	Prevalence	False-Positive Rate
Manchikanti et al 2004 (185)	80	72	42% (95% CI, 30%–53%)	55% (95% CI, 39%–78%)
Manchikanti et al 2002 (200)	80	46	48% (95% CI, 34%–62%)	58% (95% CI, 38%–78%)
Manchukonda et al 2007 (183)	70	65	34% (95% CI, 22%–47%)	42% (95% CI, 26%–59%)

Adapted and modified from Boswell MV et al. Interventional techniques: Evidence-based practice guidelines in the management of chronic spinal pain. *Pain Physician* 2007; 10:7-111 (1).

controversial: Demographic features, pain characteristics, and other signs and symptoms may not correlate and are unreliable; and medical imaging provides little useful information with radiographic investigations, including MRI, revealing only some conditions with certainty (1). The ACOEM guidelines describing extension as an indicator of facet joint pain with approval of one facet joint nerve block is based on disproven theories. Multiple authors (191,208-215) have evaluated physical examination criteria and an overwhelming proportion of these investigations have concluded in favor of the lack of reliability of physical examination in providing a precise diagnosis of facet joint pain.

The accuracy of facet joint nerve blocks is strong in the diagnosis of spinal facet joint pain (1,55,62,63,201,202,204,206,207). Minimal effects of sedation (216-219) and lack of influence of psychological factors (220,221) on the validity of controlled diagnostic local anesthetic blocks of facet joints in the cervical and lumbar spine has been demonstrated.

Though controversial, multiple therapeutic techniques have been described and established in managing chronic spinal pain of facet joint origin (1,54,222-225). While intraarticular lumbar facet joint injections in randomized controlled trials (226-228) have been shown to have limited evidence, facet joint nerve blocks (229-233) and radiofrequency neurotomy (234,235) have been shown to be moderately effective.

The authors of the ACOEM guidelines have misinterpreted the effect of sedation. ACOEM guidelines implicate that Manchikanti et al (216) concluded in their study that peri-procedure administration of sedatives may confound the results of facet joint pain. Rather, Manchikanti et al (216) concluded as follows:

The administration of sedation with midazolam or fentanyl is a confounding factor in the diagnosis of lumbar facet joint pain in patients with chronic low back pain. However, this study suggests that if strict criteria including pain relief and the ability to perform prior painful movements are used as the standard for evaluating the effect of controlled local anesthetic blocks, the diagnostic validity of lumbar facet joint nerve blocks may be preserved.

Controversies

Carragee et al (103,130) provided scathing criticism of diagnosis of axial pain syndromes, specifically with facet joint nerve blocks. While this criticism was directed at Bogduk as the senior author for King et al's study (236) and diagnostic cervical facet joint nerve blockade, it applies to all spinal diagnostic facet joint nerve blocks. Nevertheless, Bogduk (131) responded to the criticism. Review of Carragee et al's criticism and Bogduk's response illustrates that there is a lack of validity in the criticism.

Thus far, the evidence shows the validity and accuracy of facet joint nerve blocks (149,217-221,237,238). In addition, the validity of diagnostic facet joint nerve blocks has been proven based on the response to controlled, comparative local anesthetic blocks (229-233,239-241), and the diagnostic validity of lumbar facet joint nerve blocks was shown in an evaluation based on long-term response (242). Therapeutic response has been used as a gold standard by Carragee et al (88).

Based on the available literature, the alleged lack of clarity about pain generators and the potential for multiple pain generators present in a given patient, as per ACOEM, has been addressed in general in multiple studies, and in particular, in 2 studies in the lumbar spine (125,126,186,187) and one sudy (199) on the cervical spine (199).

Level of Evidence

Based on criteria utilized by ACOEM (Table 5) (33,34), the evidence base for diagnostic facet joint

nerve blocks is strong based on multiple controlled trials available in the diagnosis of spinal pain in cervical, thoracic, and lumbar region with diagnostic facet joint blocks utilizing IASP criteria.

Based on the AHRQ USPSTF criteria (Table 3) (21), the evidence level is Level I for diagnosis of chronic spinal pain of facet joint origin by diagnostic facet joint nerve blocks.

Recommendations

Based on Guyatt et al's (19) grading, the level of recommendation is 1A/strong recommendation, high-quality evidence, with benefits clearly outweighing the risks and burdens, with overwhelming evidence from observational studies as desirable for diagnostic studies, with strong recommendation which applies to most patients in most circumstances without reservation for cervical, thoracic, and lumbar diagnostic facet joint nerve blocks.

Therapeutic Facet Joint Interventions

The described therapeutic facet joint interventions incorporate intraarticular injections, medial branch blocks, and radiofrequency neurotomy.

Intraarticular Injections

ACOEM contends that the studies on therapeutic facet joint injections were not large enough and the results were inconsistent. Nevertheless, 5 randomized controlled trials were incorporated into their analysis (137,141,142,213,226).

Poor Selection Criteria and Evidence Synthesis by the ACOEM Guidelines

The randomized controlled trials included the studies by Carette et al (226), Marks et al (141), Mayer et al (137), Pneumaticos et al (213), and Lilius et al (142). However, among these, only the study by Carette et al (226) was described as of high quality. Carette et al (226) failed to exclude placebo responders, which may account for the relatively high incidence of patients in their study with presumed facet joint pain. They showed a prevalence of facet joint pain of 58% in patients with lumbar spine pain, based on inclusion criteria in Phase 1 of the study. Failure to exclude placebo responders may have diluted the findings of true responses, making detection of differences between the study and control groups difficult. The patients in the methylprednisolone group received a greater proportion of concurrent interventions. Even then, the authors concluded that at 6 months, 42% of the patients in the steroid group showed benefit compared to 15% in the sodium chloride solution group. However, they performed various types of analysis and finally concluded that there was no significant difference between the groups. The effects and consequences of intraarticular placebo injection of sodium chloride are not known. Consequently, even patients with placebo injections of sodium chloride solution responded to the treatment similar to corticosteroid injections.

Marks et al (141) compared local anesthetic and steroid in facet joint injections and facet joint nerve blocks with high volume injections. The study by Mayer et al (137) is in relation to segmental rigidity and has no relevance in managing chronic facet joint pain. The study by Pneumaticos (213) is a short-term study with no relevance to clinical practice. Finally, the study by Lilius et al (142) was poorly conducted with many flaws. In fact, Boswell et al (1) in describing evidence-based guidelines for interventional techniques only utilized Carette et al (226) for intraarticular injections.

None of the other studies were included in the evidence-based guideline preparation (1). The ACOEM guidelines have included a randomized controlled trial by Fuchs et al (227) in a separate category of facet joint hyaluronic acid injections. Sixty patients were included in this randomized, controlled, blind-observer clinical study and randomly assigned to 2 groups to receive 10 mg of sodium hyaluronate or 10 mg of triamcinolone acetonide per facet joint. The facet joints were treated under CT guidance once per week. Changes in pain were assessed with a visual analog scale (VAS) and changes in function and quality of life were assessed by the Roland-Morris Questionnaire (RMQ), the Oswestry Disability Questionnaire (ODQ), the Low Back Outcome Score (LBOS), and the Short-Form 36 (SF-36). Patients reported lasting pain relief, better function, and improved quality of life with both treatments. The responses to both sodium hyaluronate and triamcinolone acetonide were similar. The authors took many precautions to avoid bias with the same investigator making all the intraarticular injections and the outcomes assessed by a blind-observer. There was only one patient excluded from the analysis. Appropriate statistical analysis was also performed. While there were no significant differences between the groups, the mean intensity of pain on the VAS scale in the sodium hyaluronate group decreased by 40.1%, whereas, the reduction was 56.2% in the triamcino-

lone acetonide group. Significant decrease in pain-induced functional impairment and increased functional status were observed in both groups.

The disadvantages of the study include a lack of appropriate diagnosis with controlled diagnostic blocks, thus failing to exclude placebo responders which may have increased the probability of inclusion of patients without facet joint pain and, ultimately, the results. Further, pain relief of 50% or greater was achieved only in the triamcinolone group with a reduction of 51.7% despite the series of 3 injections bilaterally at 3 levels, whereas, the reduction was 45.1% in the sodium hyaluronate group. In addition, RMQ scores, ODQ scores, and LBOS showed reduction in sodium hyaluronate 43.2%, 39.1%, and 43.9%, whereas, in the triamcinolone group, the reduction was 33.4%, 29.5%, and 34.8%. They included only 30 patients in each group and have not described the proportion of patients with significant pain relief or significant functional status improvement. Further, the ACOEM guidelines also identified multiple other disadvantages which included that patients received 18 injections. While the number of injections is possibly 18, the number of episodes of injections appears to be 3, with bilateral injections at 3 levels (3x2x3=18). ACOEM authors also concluded that graphic representations suggest there are no meaningful differences in efficacy between the 2 injections. However, a significant decrease in pain-induced functional impairment and increased functional status were observed in both groups.

Boswell et al (1) excluded Marks et al (141) and also Nash (214), a study very similar to that of Marks et al's due to short-term follow-up with a single injection. Boswell et al (1) also excluded Lilius et al (142) for using overly broad criteria for inclusion without confirming the diagnosis by controlled diagnostic blocks, and for using excessive injectate volumes (3 mL to 8 mL) of active agents. Even the high quality study by Carette et al (226) for intraarticular injections did not exclude false-positives, either by using placebo controlled or controlled, comparative local anesthetic blocks.

Though not positive and faced with significant criticism, Barnsley et al (228) showed a lack of effect of intraarticular corticosteroids for chronic pain in the cervical zygapophysial joints. Notwithstanding the criticism of Carragee et al (130), their study was shown to be negative with a small number of patients with short-term follow-up. Carragee et al (130) pointed out that weaknesses in the study, which should impact on the interpretation of the findings, included the diagnostic algorithm itself and contended that there was systematic "work-up bias" in the subject evaluation, and all facet joints were not equally evaluated. Additionally, Carragee et al (130) claimed that if pain relief was reported longer by any amount (even 5 minutes) with bupivacaine (expected duration of action of 4 to 8 hours) compared to lignocaine (expected duration of action of 1 to 2 hours), the subject was reported to be "definitively diagnosed" with primary zygapophysial pain from that joint. Further, they criticized that if the duration of reported pain relief was well outside the expected pharmacologic range of several days or so, the above rule applied. Thus, Carragee et al (130) concluded that this was a scientifically inadmissible study and the ACOEM guidelines have not included this study in their analysis. Careful review of the Barnsley et al (228) manuscript shows contrary evidence. Patients were randomly selected to receive either 2% lidocaine or 0.5% bupivacaine and were not told which agent was to be administered. They rated pain relief as complete, definite, partial, or none. A progressive algorithm was used where if the pain was not relieved by the first joint, additional joints were injected until the pain was relieved or until all joints that might have been the source of pain had been tested. With the controlled, comparative local anesthetic blocks, Barnsley et al's (228) methodology included that patients had to have relief of pain on both occasions when the joint was blocked and had to have a longer period of relief with bupivacaine than with lidocaine. Further, they also enrolled 6 patients who had inordinately prolonged responses to lidocaine or both agents.

The results of this study showed the median time to return to 50% of the pre-injection level of pain was 3 days in the corticosteroid group and 3.5 days in the local anesthetic group. They were unable to demonstrate any trend in favor of either treatment.

Reassessment

Due to the poor selection criteria and evidence synthesis by the ACOEM guidelines, a reassessment was performed and a study not included by the ACOEM guidelines was also added (228).

Methodologic Quality Assessment

Methodological quality assessment is illustrated in Table 18. The total score for Carette et al (226) was 60, Fuchs et al (227) was 72, and Barnsley et al (228) was 61. Barnsley et al (228) was not included in the ACOEM guideline synthesis.

Table 18. *Methodological assessment of randomized clinical trials evaluating intraarticular facet joint injections.*

CRITERION		Weighted Score	Carette et al (226)	Fuchs et al (227)	Barnsley et al (228)
Study population					
A	Homogeneity	2	2	2	2
B	Comparability of relevant baseline characteristics	5	5	5	2
C	Randomization procedure adequate	4	4	1	4
D	Drop-outs described for each study group separately	3	3	3	3
E	≤ 20% loss for follow-up	2	2	2	2
	≤ 10% loss for follow-up	2	2	2	2
F	> 50 subject in the smallest group	8	—	—	—
	> 100 subjects in the smallest group	9	—	—	—
Interventions					
G	Interventions included in protocol and described	10	10	10	10
H	Pragmatic study	5	—	5	5
I	Co-interventions avoided	5	—	5	—
J	Placebo-controlled	5	5	0	—
Effect					
K	Patients blinded	5	5	5	5
L	Outcome measures relevant	10	10	10	5
M	Blinded outcome assessments	10	—	10	10
N	Follow-up period adequate	5	2	2	1
Data-presentation and analysis					
O	Intention-to-treat analysis	5	5	5	5
P	Frequencies of most important outcomes presented for each treatment group	5	5	5	5
	TOTAL SCORE	100	60	72	61

Methodological criteria and scoring adapted from Koes BW et al. Efficacy of epidural steroid injections for low-back pain and sciatica: A systematic review of randomized clinical trials. *Pain* 1995; 63:279-288 (51).

Results

Results of lumbar intraarticular injection studies of long-term evaluation were not available (Table 19). However, Fuchs et al (227) showed positive results for short-term of less than or up to 6 months with improvement in pain relief and functional status with steroids. Carette et al (226) also showed positive results at 6 months (15% vs 42%). No significant complications have been reported with the use of intraarticular steroid injections.

Barnsley et al (228) was the sole study available for cervical intraarticular facet joint injections which showed negative results for short-term. Long-term results were not available.

Level of Evidence

Based on the ACOEM guidelines (Table 5) (33) quality of evidence synthesis, there is a limited evidence base with one study of moderate quality (Level C) for managing lumbar facet joint pain, whereas, based on quality of evidence developed by AHRQ USPSTF (Table 3) (21), evidence is Level I with evidence obtained from well-designed controlled trials for short-term.

Table 19. *Results of randomized trials of effectiveness of intraarticular facet joint interventions.*

Study	Study Characteristics	Methodological Quality Scoring		Participants	Pain Relief				Results	
		ACOEM Score x 9.1	Reassessment Score		≤ 3 mos	3 mos	6 mos	12 mos	Short-term relief ≤ 6 mos	Long-term relief > 6 mos
Lumbar										
Carette et al 1991 (226)*	PC, RA, DB	73	60	C=48 T=49	33% vs 42%	NA	15% vs 42%	NA	N	NA
Fuchs et al 2005 (227)*	RA, DB	63.7	72	SH=30 TA=30	SI	SI	SI	NA	P	NA
Cervical										
Barnsley et al 1994 (228)	RA, DB	NUA	61	41	50%	NA	NA	NA	N	NA

* Indicates use in ACOEM guidelines.
RA = randomized; PC = placebo controlled; DB = double blind; C = control; T = treatment; SI = significant improvement; SH = sodium hyaluronate; TA = triamcinolone acetonide; P = positive; N = negative, NA = not available; NUA = not utilized in analysis by authors of ACOEM guidelines

Adapted and modified from Boswell MV et al. Interventional techniques: Evidence-based practice guidelines in the management of chronic spinal pain. *Pain Physician* 2007; 10:7-111 (1).

There are no randomized trials available to assess long-term relief of 6 months or longer.

For cervical intraarticular injections, there is no significant evidence, either for short-term or long-term relief.

Recommendations

Based on Guyatt et al's (19) recommendation for lumbar intraarticular injections for short-term relief, the evidence is 1B or 1C/strong recommendation with moderate or very low quality evidence with benefits clearly outweighing the risks, evidence obtained from randomized controlled trials with important limitations or observational studies or case series with overall strong recommendation which can apply to most patients in most circumstances without reservation. However, the recommendation may change when higher quality evidence becomes available.

For cervical intraarticular injections, there is no significant evidence, either for short-term or long-term. Thus, there is no recommendation derived from Guyatt et al's (19) grading criteria.

Medial Branch Blocks

The ACOEM guidelines have not included the role of therapeutic medial branch blocks. Spinal facet joint nerve blocks (medial branch blocks) have been described as an alternative to percutaneous radiofrequency neurotomy in managing chronic spinal pain (54,61,229-233).

Assessment of Evidence

Since the ACOEM guidelines have missed inclusion of therapeutic medial branch blocks, an assessment of therapeutic medial branch blocks was undertaken. The role of therapeutic medial branch blocks has been described in multiple manuscripts, systematic reviews, and guidelines (1,9,54,61,85-87,229-233), with moderate evidence in the cervical and lumbar spine.

Methodologic Quality Assessment

Methodological quality assessment is described in Table 20 with the assessment based on the criteria established by Cochrane review and described by Koes et al (51), with quality rating criteria of 68, 68, and 60 for studies involving cervical, lumbar, and thoracic regions.

Study Characteristics

Manchikanti et al (230) in a randomized, double-blind, controlled trial of lumbar facet joint nerve blocks in managing chronic facet joint pain demonstrated significant improvement with significant pain relief and functional improvement of greater than 40% in approximately 80% of the patients with either local anesthetic alone or local anesthetic with steroids.

Table 20. *Methodological assessment of randomized clinical trials therapeutic role of medial branch blocks.*

CRITERION		WEIGHTED SCORE	Manchikanti et al (230)	Manchikanti et al (232)	Manchikanti et al (233)
Study population					
A	Homogeneity	2	2	2	2
B	Comparability of relevant baseline characteristics	5	2	2	2
C	Randomization procedure adequate	4	4	4	4
D	Drop-outs described for each study group separately	3	3	3	3
E	≤ 20% loss for follow-up	2	2	2	2
	≤ 10% loss for follow-up	2	2	2	2
F	> 50 subject in the smallest group	8	8	8	—
	> 100 subjects in the smallest group	9	—	—	—
Interventions					
G	Interventions included in protocol and described	10	10	10	10
H	Pragmatic study	5	5	5	5
I	Co-interventions avoided	5	—	—	—
J	Placebo-controlled	5	—	—	—
Effect					
K	Patients blinded	5	5	5	5
L	Outcome measures relevant	10	10	10	10
M	Blinded outcome assessments	10	—	—	—
N	Follow-up period adequate	5	5	5	5
Data-presentation and analysis					
O	Intention-to-treat analysis	5	5	5	5
P	Frequencies of most important outcomes presented for each treatment group	5	5	5	5
	TOTAL SCORE	**100**	**68**	**68**	**60**

Methodological criteria and scoring adapted from Koes BW et al. Efficacy of epidural steroid injections for low-back pain and sciatica: A systematic review of randomized clinical trials. *Pain* 1995; 63:279-288 (51).

In this study, 120 patients were evaluated with 60 patients in each group with appropriate outcome measures and assessments at 3, 6, and 12 months (Table 21). A preliminary report (229) was published prior to the publication of the ACOEM guidelines.

The advantages of this study include a pragmatic study utilizing 60 patients in each group in a non-academic setting, which was also randomized and double-blind with appropriate and relevant outcome measures provided at various treatment points. The disadvantages include a lack of placebo control and a single center study.

Manchikanti et al (232) also studied the role of therapeutic cervical medial branch blocks. All of the patients met the diagnostic criteria of cervical facet joint pain by means of comparative, controlled diagnostic blocks and the inclusion criteria. The results showed that significant pain relief (> 50%) and functional status improvement was observed at 3, 6, and 12 months in over 83% of the patients. The average number of treatments was 3 to 4 per year with average pain relief with each procedure of 14 to 16 weeks associated with significant pain relief and functional improvement for 46 to 48 weeks in a year (Table 21). A preliminary report was published in 2006 (231).

The advantages of this study include the inclusion of 60 patients in each group in a non-academic setting in a randomized and double-blind trial with appropriate and relevant outcome measures provided at various treatment points, in a pragmatic study. The

Table 21. *Results of randomized trials of effectiveness of therapeutic facet joint nerve blocks.*

Study	Study Characteristics	Methodological Quality Scoring		Participants	Pain Relief			Results	
		ACOEM Score x 9.1	Reassessment Score		3 mos	6 mos	12 mos	Short-term relief ≤ 6 mos	Long-term relief > 6 mos
Lumbar									
Manchikanti et al 2008 (230)	RA, DB	NUA	68	Group I-no steroid=60 Group II-steroid=60	83% vs 82%	83% vs 93%	82% vs 85%	P	P
Cervical									
Manchikanti et al 2008 (232)	RA, DB	NUA	68	Group I-no steroid=60 Group II-steroid=60	83% vs 85%	87% vs 95%	85% vs 92%	P	P
Thoracic									
Manchikanti et al 2008 (233)	RA, DB	NUA	60	Group I-no steroid=24 Group II-steroid=24	79% vs 83%	79% vs 81%	79% vs 79%	P	P

RA = randomized; DB = double blind; vs=versus; P = positive; N = negative, NUA = not utilized in analysis by authors of ACOEM guidelines

Adapted and modified from Boswell MV et al. Interventional techniques: Evidence-based practice guidelines in the management of chronic spinal pain. *Pain Physician* 2007; 10:7-111 (1).

disadvantages include a lack of placebo control, lack of blinded observer, and a single center study.

In a study which was not available at the time of publication of the ACOEM guidelines, the effectiveness of thoracic medial branch blocks were studied in a randomized, double-blind controlled evaluation (233). However, if the ACOEM authors had searched appropriately, the study was listed on Controlled Trial Registry and would have provided the possibility of contacting the authors. In addition, a prospective evaluation was published (241). Manchikanti et al (233) reported preliminary results of the effectiveness of thoracic medial branch blocks in managing chronic pain, in a randomized, double-blind controlled trial, illustrated the results of 48 patients with 24 patients in each group receiving either local anesthetic or steroid. The inclusion criteria were diagnosis of thoracic facet joint pain by means of comparative, controlled diagnostic blocks. The outcome measures included numeric pain scores, Oswestry Disability Index (ODI), opioid intake, and return to work status with assessment of all outcomes at baseline, 3, 6, and 12 months. The results showed the majority of the patients with significant improvement in pain relief (> 50%) and functional status improvement. Patients receiving only local anesthetic in Group I showed significant pain relief and functional improvement of 79% at 3, 6, and 12 months. In Group II, patients receiving bupivacaine with steroids for medial branch blocks showed improvement of 83%, 81%, and 79% at 3, 6, and 12 months. Based on the results of this study, it appears that patients may experience significant pain relief of 46 to 50 weeks of a year, requiring approximately 3 to 4 treatments with an average relief of 16 weeks per episode of treatment.

The advantages of this study include a randomized, double-blind, pragmatic design in a non-academic setting with appropriate and relevant outcome measures provided at various treatment points. The disadvantages include the small number of patients, lack of placebo control, and a single center study.

Level of Evidence

Based on the present evaluation and the criteria of quality of evidence utilized by ACOEM (Table 5) (33), evidence is Level B with moderate evidence base with at least one high-quality study relevant to the topic and the working population. Based on the quality of evidence developed by AHRQ USPSTF (Table 3)

(21), the evidence is Level I with evidence from at least one properly randomized controlled trial.

Recommendations

Based on Guyatt's (19) recommendations, grading for cervical and lumbar medial branch blocks is 1A or 1B/strong recommendation, with benefits clearly outweighing the risks and burdens with evidence presented in randomized controlled trials without important limitations with a strong recommendation, which can apply to most patients in most circumstances without reservation for cervical and lumbar therapeutic facet joint nerve blocks.

However, for thoracic medial branch blocks, the recommendation is 1B or 1C/strong recommendation, which may apply to most patients in most circumstances without reservation but may change when higher quality evidence becomes available.

Radiofrequency Neurotomy

The ACOEM guidelines chronic pain chapter also described radiofrequency neurotomy. They concluded that cervical radiofrequency neurotomy is ineffective based on the rate of false-positive facet joint injections in the cervical spine estimated at 27% (138). The guidelines (34) contend that there is a lack of clarity about the pain generators, and the potential for multiple pain generators is present in a given patient. The ACOEM guidelines (34) claimed that the prevalence of this disorder is quite unclear and likely varies widely, particularly from primary to tertiary patient care settings and has been estimated at 25% to 50% (139,140). The authors of the ACOEM guidelines stated that most of the studies are in the lumbar spine and they did not recommend radiofrequency neurotomy for cervicogenic headaches or any spinal condition (33,34).

Poor Selection Criteria and Evidence Synthesis by the ACOEM Guidelines

The ACOEM rationale for recommendation is based on presumably multiple quality studies which have been questioned by others. They quoted 2 studies managing cervicogenic headache, which were negative (243,244). For spine pain, the highest quality studies quoted were of Leclaire et al (245) and van Wijk et al (246). They considered the study by van Kleef et al (234) as lower quality. They also considered a study by Gallagher et al (247) as lower quality. They quoted a review by Hooten et al (248), which discussed additional, significant methodological concerns. Importantly, the ACOEM guidelines state that this procedure causes Charcot joints by permanently denervating the joints (33,34). Further, the guidelines consider that the number of patients that could be successfully treated with this therapy is small.

The ACOEM guidelines utilized studies evaluating facet joint pain with cryoneurolysis (143) and intraarticular and extraarticular facet joint denervation (249), a study comparing temperature-controlled lumbar radiofrequency with voltage-controlled lumbar radiofrequency (250), and radiofrequency thermocoagulation of ramus communicans nerve (251).

Systematic Reviews and Contrasting Evidence

There have been multiple systematic reviews of medial branch radiofrequency neurotomy (54,61,222-225,252), guidelines (1,85-87), a technology assessment (253), randomized trials (234,235), and quality observational studies (254-257). Boswell et al's (1) evidence-based guidelines for interventional techniques, after extensive review, utilized only 3 systematic reviews (54,225,252) and excluded 2 (222,223). Thus, the ACOEM guidelines lacked critical evaluation of the literature. Geurts et al (222) concluded that there was moderate evidence that radiofrequency lumbar facet denervation was more effective for chronic low back pain than placebo, and there was only limited evidence for the effectiveness of radiofrequency neurotomy for chronic cervical zygapophysial joint pain after flexion/extension injury. Manchikanti et al (225) concluded that there was strong evidence for short-term relief and moderate evidence for long-term relief of facet joint pain. Niemesto et al (223), within the framework of the Cochrane Collaboration Back Review Group, concluded that there was limited evidence that radiofrequency denervation had a positive short-term effect on chronic cervical zygapophysial joint pain, and a conflicting short-term effect on chronic low back pain. Murtagh and Foerster (253) concluded that radiofrequency neurotomy continues to be an emerging technology, with some studies suggesting it is efficacious, but procedural and other methodological shortcomings render much of this research inconclusive. Slipman et al (252) concluded that the evidence for radiofrequency denervation in managing chronic lumbar zygapophysial joint pain was moderate.

The systematic reviews by Manchikanti et al (225) and Boswell et al (54) evaluated the effectiveness of facet joint neurotomy utilizing the criteria established by the AHRQ for evaluation of randomized and non-randomized trials and Cochrane Musculoskeletal Review

Group for randomized trials. They concluded that the evidence for pain relief with radiofrequency neurotomy of medial branch nerves was moderate to strong in the cervical and lumbar spine. Slipman et al (252) also utilized criteria by AHRQ. Boswell et al (1,54) in the evaluation of the role of medial branch neurotomy, evaluated 8 randomized trials and 18 observational studies. However, of these, only 2 randomized trials (234,235) met the inclusion criteria. Six of the 8 randomized trials were excluded because of inappropriate inclusion criteria, inappropriate diagnostic evaluation, inappropriate interventions, or inadequate follow-up. The majority of these excluded studies were included in the synthesis of the ACOEM guidelines as they continue to be negative, even though there were fatal flaws. The ACOEM guidelines failed to include an excellent cervical medial branch neurotomy study performed by Lord et al (235) with positive results. Boswell et al (1,54) excluded Haspeslagh et al (244), Van Wijk et al (246), Gallagher et al (247), Leclaire et al (245), Sanders and Zuurmond (249), and Buijs et al (250).

Poor Methodologic Quality of Studies Included in the ACOEM Guidelines

Haspeslagh et al (244) evaluated radiofreqency for cervicogenic headache with 15 patients receiving a sequence of radiofrequency treatments with cervical facet joint denervation, followed by cervical dorsal root ganglion lesions when necessary, and the other 15 patients undergoing local injections with steroid and anesthetic at the greater occipital nerve, followed by transcutaneous electrical nerve stimulation (TENS) when necessary. They concluded that they did not find evidence that radiofrequency treatment of cervical facet joints and upper dorsal root ganglion is a better treatment than infiltration of greater occipital nerve, followed by TENS for patients fulfilling the clinical criteria of cervicogenic headache. Obviously this study is totally flawed, not only in the diagnosis, but also the application of technique. The authors claimed that they developed a sequence of various cervical radiofrequency neurotomies that proved successful in a prospective pilot trial with 15 chronic headache patients. Their diagnosis was not established by controlled diagnostic blocks. Further, their treatments were targeting 2 different structures, namely cervical facet joints and cervical root ganglion compared to occipital nerves; thus, this study was excluded by Boswell et al (1,54).

van Wijk et al (246), in a study which appears elegant and technically competent, described radiofrequency denervation of lumbar facet joints in the treatment of chronic low back pain. The randomized, double-blind, sham-controlled trial evaluated a total of 81 out of 462 patients randomly assigned to radiofrequency denervation or sham treatment. Overall, they concluded that the combined outcome measure and VAS showed no difference between radiofrequency and sham, though in both groups, significant VAS improvements occurred. They also concluded that in selected patients, radiofrequency facet denervation appears to be more effective than sham treatment. More recently, they have also published another paper evaluating psychological predictors of substantial pain reduction in these patients based on so-called negative data (258). In addition, the technical aspects of the procedure have been criticized (259,260). Further, the study was compared with an observational study performed by Dreyfuss et al (254) meticulously utilizing controlled, comparative local anesthetic blocks for diagnosis.

Leclaire et al (245) also published what appeared to be an elegant, well-performed, double-blind, placebo-controlled trial, similar to the one by van Wijk et al (246). This study had multiple deficiencies such as failing to define the study population and using inappropriate diagnostic criteria, which was a fatal error (1,54). Further, patients were evaluated with a single diagnostic block with 50% pain relief as a criterion standard. These authors considered any relief of one day duration during a 7-day period following a single diagnostic block as significant. This type of pain relief may be a result of many other factors, including natural sequence. Consequently, any results or conclusions based on this study would be erroneous (261). Gallagher et al (247) used an invalidated Shealy technique, and also failed to describe appropriate diagnostic techniques and outcome analysis. In addition, it is unclear whether these interventions were performed with or without fluoroscopy. Other studies excluded from Boswell et al's (1,54) evidence synthesis were Sanders and Zuurmond (249) utilizing intraarticular and extraarticular radiofrequency and Buijs et al (250) comparing reproducibility of lesion size of 2 current radiofrequency techniques.

The authors of the ACOEM guidelines (33,34) have decided for the wrong reasons to include all the studies which were excluded by others and have done an inadequate evaluation and literature search. They (34) excluded Lord et al's (235) trial evaluating percutaneous radiofrequency neurotomy in patients with cervical facet joint pain, diagnosed with controlled, comparative local anesthetic blocks, in a double-blind,

placebo-controlled trial. The authors concluded that in patients with chronic cervical facet joint pain, percutaneous radiofrequency neurotomy with multiple lesions of target nerves can provide long-lasting relief. van Kleef et al (234) also demonstrated that radiofrequency denervation of the lumbar facet joints can be effective for pain reduction in patients with lumbar facet joint pain.

Reassessment

Based on the lack of appropriate evidence-based analysis and synthesis of radiofrequency neurotomy, a reassessment of the evaluation was carried out.

Methodologic Quality Assessment

Only 3 studies met inclusion criteria (234,235,262). In contrast, the ACOEM guidelines utilized multiple studies (234,244-247,249,250), some described as high quality, which did not meet established inclusion criteria. Consequently, no methodologic quality assessment was performed on these studies. Of the 3 studies meeting inclusion criteria (234,235,262), only the study by van Kleef et al (234) was utilized by ACOEM. Nath et al (262) was published in 2008. Methodologic quality criteria are illustrated in Table 22 with quality criteria of 73 for van Kleef's study (234), 64 for Lord et al's study (235), and 70 for Nath et al's study (262).

Table 22. *Methodological assessment of randomized clinical trials evaluating the effectiveness of radiofrequency neurolysis of facet joint nerves.*

	CRITERION	WEIGHTED SCORE	Van Kleef et al (234)	Lord et al (235)	Nath et al (262)
Study population					
A	Homogeneity	2	2	2	2
B	Comparability of relevant baseline characteristics	5	5	3	5
C	Randomization procedure adequate	4	4	4	4
C	Drop-outs described for each study group separately	3	3	3	3
E	≤ 20% loss for follow-up	2	2	2	2
	≤ 10% loss for follow-up	2	2	2	2
F	> 50 subject in the smallest group	8	—	—	—
	> 100 subjects in the smallest group	9	—	—	—
Interventions					
G	Interventions included in protocol and described	10	10	10	10
H	Pragmatic study	5	5	5	5
I	Co-interventions avoided	5	—	—	—
J	Placebo-controlled	5	—	—	—
Effect					
K	Patients blinded	5	5	5	5
L	Outcome measures relevant	10	10	8	10
M	Blinded outcome assessments	10	10	8	10
N	Follow-up period adequate	5	5	2	2
Data-presentation and analysis					
O	Intention-to-treat analysis	5	5	5	5
P	Frequencies of most important outcomes presented for each treatment group	5	5	5	5
	TOTAL SCORE	100	73	64	70

Methodological criteria and scoring adapted from Koes BW et al. Efficacy of epidural steroid injections for low-back pain and sciatica: A systematic review of randomized clinical trials. *Pain* 1995; 63:279-288 (51).

Study Characteristics

Despite the criticism by the ACOEM guidelines and Carragee et al (130), Lord et al (235) is a scientifically admissible study and radiofrequency neurotomy was shown to be effective. Carragee et al (130) criticized the differences in baseline characteristics of patients among both groups. However, the authors had no influence on the selection due to a randomization protocol. The results showed no significant differences based on these differences and also based on litigation. The results showed that 58% of the patients in the control group and 25% in the active-treatment group had a return of their accustomed pain in the period immediately after the radiofrequency procedure at the 3 month follow-up. Seven patients in the radiofrequency group and 3 patients in the control group reported significant pain relief, i.e., 25% vs. 58%. By 27 weeks, one patient in the control and 7 in the active treatment group remained free of pain (8% vs. 58%). Consequently, this study illustrated a well established diagnostic approach prior to intervention and significant improvement. The disadvantages include local anesthetic injection, which is not a true placebo, prior to radiofrequency neurotomy. Further, the numbers were very small. However, all the factors are considered in methodologic quality assessment criteria with a score of 64.

The second study which was rated as moderate quality by van Kleef et al (234) was assessed to have a methodological score of 63.7 by ACOEM and 73 in the present reassessment. Even then, the authors concluded that there was no evidence for radiofrequency neurotomy. van Kleef et al (234) studied 31 patients with a history of at least one year of chronic low back pain on the basis of a positive response to a single diagnostic nerve block and subsequently randomly assigned to one of 2 treatments. They reported significant improvement in 67% of the patients receiving radiofrequency and 38% of the patients in the control group. At 3 months, the relief was seen in 25% of the control group and 60% of the radiofrequency group, whereas, it decreased to 19% and 13% in the control group at 6 months and 12 months and to 47% at both time periods in radiofrequency group. The disadvantages of this study include a lack of controlled diagnostic blocks to eliminate false-positive responses, a small number of patients, and lack of a placebo group.

The third study by Nath et al (262) published in 2008 achieved a methodological score of 70. This study evaluated percutaneous lumbar zygapophysial (facet) joint neurotomy using radiofrequency current, in the management of chronic low back pain in a randomized, double-blind design. Their main aim

Table 23. *Results of randomized trials of effectiveness of radiofrequency neurolysis of facet joint nerves.*

Study	Study Characteristics	Methodological Quality Scoring		Participants	Pain Relief			Results	
		ACOEM Score x 9.1	Reassessment Score		3 mos	6 mos	12 mos	Short-term relief ≤ 6 mos	Long-term relief > 6 mos
Lumbar									
Van Kleef et al 1999 (234)*	PC, RA, DB	63.7	73	C=16 T=15	25% vs 60%	19% vs 47%	13% vs 47%	P	P
Nath et al 2008 (262)	PC, RA, DB	NUA	70	C=20 T=20	SI	SI	NA	P	NA
Cervical									
Lord et al 1996 (235)	PC, RA, DB	NUA	64	LA=12 RFTN=12	25% vs 58%	8% vs 58%	8% vs 58%	P	P

* Indicates use in ACOEM guidelines.
RA = randomized; PC = placebo controlled; DB = double blind; NUA = not utilized in analysis by authors of ACOEM guidelines; C = control; T = treatment; LA = local anesthetic; RFTN = radiofrequency thermoneurolysis; vs = versus; P = positive; SI = significant improvement; NA = not available;
Adapted and modified from Boswell MV et al. Interventional techniques: Evidence-based practice guidelines in the management of chronic spinal pain. *Pain Physician* 2007; 10:7-111 (1).

was to prove that radiofrequency facet denervation is not a placebo. They included only patients after 3 separate positive facet blocks with 20 patients in the control group and 20 patients in the experimental group. The active treatment group showed statistically significant improvement not only in back and leg pain, but also back and hip movement, as well as the sacroiliac joint test. There was also significant improvement in quality of life variables, global perception of improvement, and generalized pain. The improvement seen in the active group was significantly greater than that seen in the placebo group. This is a well conducted study with appropriate diagnostic criteria. The drawbacks of the study include a small number of patients with 20 in each group and only a short-term or 6-month follow-up rather than long-term follow-up.

Table 23 illustrates results of randomized trials of effectiveness of radiofrequency neurolysis of facet joint nerves.

Level of Evidence

Based on the ACOEM quality of evidence criteria (Table 5) (33), the evidence category is B – moderate, with evidence based on at least one high quality study, in managing cervical and lumbar facet joint pain. Based on AHRQ USPSTF (21) quality of evidence, it falls into either I or if downgraded into II-1.

Recommendations

For cervical and lumbar radiofrequency neurotomy, based on Guyatt et al's (19) criteria, the recommendation is 1B or 1C/strong recommendation, moderate quality evidence, with benefits clearly outweighing risks and burdens, with methodologic quality of supporting evidence from a randomized controlled trial with important limitations, procedures are recommended strongly with recommendation applying to most patients in most circumstances, without reservation, but which may be changed based on change in evidence.

Epidural Injections

While the literature on the effectiveness of epidural steroid injections is mixed (1,50-54,56, 65,66,85-87,263-266), the ACOEM guidelines recommended epidural steroid injections for acute or subacute radicular pain syndromes for the purpose of a few weeks of partial pain relief while awaiting spontaneous improvement (33,34). The second recommendation was for acute flare-ups of spinal stenosis with insufficient evidence. Epidural glucocorticosteroid injections were not recommended for acute, subacute, or chronic low back pain without radicular symptoms. The ACOEM guidelines accurately recommend that the "series of 3" be abandoned, even though they confuse the issue with a discussion of a fourth injection.

The rationale for their recommendation was based on multiple systematic reviews which arrived at contradictory conclusions (33,34). The authors of the ACOEM guidelines state that those studies with the highest standards for evidence have generally not found epidurals to be a cost effective treatment. Most of the randomized controlled trials have studied blind interlaminar epidural injections, while fluoroscopic guidance may have improved the results (which has not been directly tested) (33,34). They described 4 high quality studies that evaluated patients in the 4 to 6 weeks time frame, demonstrating that these injections are helpful to reduce short-term leg and back pain ratings for those with herniated intervertebral discs (33,34,267-270). Based on these studies, they concluded that there was no evidence to suggest any functional improvement or reduction in need for surgery (33,34). The ACOEM guidelines describe that it should be recognized that the purpose of epidurals for acute radicular pain syndromes is perhaps best stated as "buying time" through a period of natural recovery (33,34). They have not provided any evidence for this conclusion. Further, none of the studies included in the interlaminar group utilized fluoroscopy, whereas only one study (33) in the caudal group utilized fluoroscopy for endoscopy.

The ACOEM guidelines also reported 2 moderate quality randomized controlled trials showing that these injections help symptoms of spinal stenosis (33,34,271,272), though on a short-term basis. The authors also described that there is no evidence to obtain an MRI or CT prior to an epidural injection (267,269,273). Further, the guidelines (33,34) described 12 high and moderate-quality randomized controlled trials, 13 systematic reviews, 4 guidelines, and 9 low-quality studies, including the additions to the appendix section. The studies of high and moderate quality randomized controlled trials included in the evaluation studied transforaminal, interlaminar, and caudal approaches (267-272,274-279). However, the outcomes of approach were not separated.

Thus, the ACOEM authors have inappropriately combined all 3 approaches, and have not described the role of cervical interlaminar epidural steroid injections. Substantial differences exist between the 3 approaches to the epidural space. They also used references incorrectly (54,66,273,280-282).

Boswell et al (1) considered all relevant quality systematic reviews (50-54,264,265) along with randomized and non-randomized trials for each category. Defining the short-term effect as significant relief (≥ 50%) of less than 6 weeks and long-term effect as 6 weeks or longer relief, they concluded that the evidence for caudal epidural steroid injections was moderate for long-term relief in managing chronic low back and radicular pain, and limited in managing pain of post-lumbar laminectomy syndrome. Further, the evidence for interlaminar epidural steroid injections was limited for long-term relief in managing lumbar radiculopathy, whereas, for cervical radiculopathy, the evidence was moderate. They also showed that the evidence for transforaminal epidural injections was moderate for long-term improvement in managing lumbar nerve root pain, whereas, it was moderate for cervical nerve root pain and limited in managing pain secondary to lumbar post-laminectomy syndrome and spinal stenosis. Thus, inappropriate evaluation without specific consideration of the 3 routes of administration for 3 regions have produced flawed results (1,50-54,56,65,66,85-87,263-266). However, after appropriate analysis, others (1,56,65,66,85-87,263), in systematic reviews, guidelines, and comprehensive reviews, evaluated caudal epidural injections as a separate procedure and reached opposite conclusions, with higher ratings of the evidence.

Consequently, in this reassessment, caudal, lumbar interlaminar, cervical interlaminar, and lumbar transforaminal approaches were evaluated separately.

Caudal Epidural Injections

Poor Selection Criteria and Evidence Synthesis by the ACOEM Guidelines

Of the 8 randomized trials (275,277,283-288) evaluating caudal epidural injections utilized by Boswell et al (1) and Abdi et al (56), the ACOEM guidelines (33,34) utilized only 2 (275,277). Boswell et al (1) and Abdi et al (56) excluded 3 studies from evidence synthesis, due to non-availability of analyzable information (289), due to a lack of data at 3 months (290), and due to a lack of appropriate data and non-use of fluoroscopy in a study which was performed in 2005 (291). Of the remaining 8 randomized trials, 6 trials evaluated predominantly patients with disc herniation or radiculitis (275,277,283,284,287,288), 2 trials (285,286) evaluated post surgery syndrome, one study (288) evaluated a mixed population with 50% post surgery syndrome and the other 50% with sciatica, and one study (287) evaluated similarities between interlaminar and caudal epidural injections. Consequently, 4 of the 6 trials of disc herniation or radicular pain were positive for long-term relief (275,277,283,288), whereas, only one (285) of the 2 trials (285,286) for post surgery syndrome was positive for short-term relief only.

Boswell et al's guidelines (1), the systematic review by Abdi et al (56), and the ACOEM's guidelines (33,34) included a study by Dashfield et al (275), which was performed under fluoroscopic visualization. In this study, caudal epidural steroids were compared with targeted steroid placement during spinal endoscopy for chronic sciatica in a prospective, randomized, double-blind trial. In this study, for the caudal group significant improvements were found for descriptive pain at 6 months, as well as VAS at 6 weeks, 3 months, and 6 months. This study also showed present pain intensity improvements at 3 months and 6 months along with improvements in anxiety at 6 weeks, 3 months, and 6 months, and depression at 6 months only. The authors concluded that the targeted placement of epidural steroid onto the affected nerve root causing sciatica does not significantly reduce pain intensity and anxiety and depression compared with untargeted caudal epidural steroid injection. However, patients of both techniques benefited. This study essentially demonstrated that in patients who have not had surgical intervention in the past, epidural steroid injections are more effective than targeted placement with endoscopy. Consequently, this study is considered as a negative study for spinal endoscopy in patients without previous surgical intervention and a positive study for caudal epidural steroid injections. In contrast, the ACOEM guidelines utilized the same evidence and reversed it. They (33,34) quote Dashfield et al's (275) conclusion that the theoretical advantages of spinal endoscopy that allows identification of the nerve root response flow for pain generation and accurate placement of local anesthetic and steroid were not translated into clinical practice. This statement is only appropriate in evaluation of the role of spinal endoscopy in non-surgical patients. They have not considered the physical trauma, especially to neurological structures, with a spinal endoscope and its associated manipulation, compared to a caudal epidural

injection with the least trauma.

In fact, this study shows positive effects of caudal epidural when administered without the mechanical trauma in patients without surgical intervention.

The ACOEM guidelines also utilized a 1978 study by Mathews et al (277) comparing caudal epidural injections with methylprednisolone acetate 80 mg and 20 mL of bupivacaine versus 2 mL injections of lignocaine among 57 patients with clinical sciatica. At one-month, 67% of epidural patients versus 56% of patients in the control group had recovered, and at 3 months there was statistical significance in favor of epidural injections with no significant differences at one year for the report of having had no further pain. Overall this study was considered of poor quality by ACOEM (33) with a claim that researchers failed to distinguish clinical sciatica appropriately.

Reassessment

Based on the evaluation by the ACOEM guidelines, with inaccurate methodology and poor selection criteria, this reassessment included only caudal epidural injections in this part of the evaluation. The ACOEM guidelines eliminated Breivik et al (283), Bush and Hillier (284), Hesla and Breivik (288), and Revel et al (285).

Table 24. *Methodological assessment of randomized clinical trials evaluating the effectiveness of caudal epidural injections*

CRITERION		WEIGHTED SCORE	Dashfield et al* (275)	Mathews et al (277)	Breivik et al (283)	Bush and Hillier (284)	Hesla and Breivik (288)	Revel et al (285)
Study population								
A	Homogeneity	2	2	1	1	2	1	2
B	Comparability of relevant baseline characteristics	5	5	3	2	3	3	3
C	Randomization procedure adequate	4	4	4	4	1	4	1
D	Drop-outs described for each study group separately	3	3	3	3	3	3	3
E	≤ 20% loss for follow-up	2	2	2	2	—	2	—
	≤ 10% loss for follow-up	2	2	2	2	—	2	—
F	> 50 subject in smallest group	8	—	—	—	—	—	—
	> 100 subjects in smallest group	9	—	—	—	—	—	—
Interventions								
G	Interventions included in protocol and described	10	10	10	10	10	10	10
H	Pragmatic study	5	5	—	5	—	5	5
I	Co-interventions avoided	5	—	5	5	—	5	—
J	Placebo-controlled	5	—	4	5	5	—	—
Effect								
K	Patients blinded	5	2	3	3	3	5	5
L	Outcome measures relevant	10	6	4	6	3	3	10
M	Blinded outcome assessments	10	2	10	10	—	—	10
N	Follow-up period adequate	5	2	1	—	5	5	3
Data-presentation and analysis								
O	Intention-to-treat analysis	5	—	5	5	—	5	5
P	Frequencies of most important outcomes presented for each treatment group	5	5	5	5	5	5	5
TOTAL SCORE		**100**	**50**	**62**	**68**	**40**	**58**	**62**

* fluoroscopy was utilized

Methodological criteria and scoring adapted from Koes BW et al. Efficacy of epidural steroid injections for low-back pain and sciatica: A systematic review of randomized clinical trials. *Pain* 1995; 63:279-288 (51).

Methodologic Quality Assessment

Table 24 illustrates methodological assessment of randomized controlled trials evaluating caudal epidural injections. Only 2 studies were included in the ACOEM guidelines. These were by Dashfield et al (275) and Mathews et al (277). Methodologic quality of criteria scores for the remaining of the studies were highly variable from 40 to 68.

Of the 6 studies meeting inclusion criteria for caudal epidural injections, 5 of them scored 50 or higher, except one study by Bush and Hillier (284) which scored 40. Consequently, it was not included in the evidence rating.

Study Characteristics

Table 25 illustrates characteristics of various studies included in randomized assessment.

Results

Results (Table 26) of this evaluation showed long-term relief of more than 6 months in both of the available studies (277,288); whereas long-term data was not available in 3 studies (275,283,285). Five studies with a reassessment score of 50 or higher (275,277,283,285,288) were included in the evidence synthesis. Thus, 4 of the 5 studies with methodologic quality scores of 50 or higher showed positive results for short-term relief (≤ 6 months), except Mathews et al (277) which showed negative results. The study with low scores on methodologic quality assessment by Bush and Hillier (284) also showed positive results, both for short-term and long-term.

These studies included patients with disc herniation, radiculitis, and post lumbar laminectomy syndrome. However, elimination of the study (285) with post laminectomy syndrome and the patients with post laminectomy syndrome from another study (288) also has not changed the evidence level in managing disc herniation and radiculitis both for short-term or long-term (≤ or > 6 months).

Helsa and Breivik (288) showed positive evidence in 50% of previously operated patients compared to 70 – 80% of patients without previous back surgery in the experimental group receiving steroid and bupivacaine. In contrast, the Revel et al (285), in a study of 60 post-lumbar laminectomy patients with chronic low back pain showed improvement in 49% of the patients with forceful injection group compared to 19% in the control group with a 6-month follow-up. Consequently, these studies show value for caudal epidural injections even in patients of post-lumbar laminectomy syndrome.

Level of Evidence

Based on this reassessment, utilizing the same criteria as the ACOEM guidelines, results are positive in 3 of 4 studies with quality assessment criteria of 50 or higher for short-term relief of 6 months or less, whereas, 2 of 2 are positive for long-term of > 6 months indicating strong evidence (19,23) for caudal epidural injections in managing pain of disc herniation and radiculitis. However, the evidence for caudal epidural injections based on ACOEM guidelines criteria (33) (Table 5) is moderate for short-term relief for post lumbar laminectomy syndrome and limited for long-term relief for post lumbar laminectomy syndrome based on 2 studies (285,288).

Based on quality of evidence developed by AHRQ USPSTF (Table 3) (21), the evidence is Level I. The evidence is Level I in managing pain secondary to disc herniation and radiculitis with caudal epidural injections. However, in managing post lumbar laminectomy syndrome, the evidence for caudal epidural injections is Level II-1 for short term relief of 6 months or less and evidence is Level II-2 for long-term relief. of > 6 months.

Recommendations

Based on the methodological assessment and quality of evidence and grading recommendations by Guyatt et al (Table 2) (19), the recommendation for caudal epidural steroid injections in managing disc herniation and radiculitis is 1A/strong recommendation with high quality evidence, with benefits clearly outweighing risks and burdens, methodological quality of supporting evidence derived from randomized controlled trials, with strong recommendation, which applies to most patients in most circumstances without reservation.

Based on Guyatt et al's (19) recommendations, the recommendation for caudal epidural steroid injections in managing patients with post lumbar laminectomy is 1C/strong recommendation with low quality or very low quality evidence, however benefits clearly outweighing the risks and burdens, supporting evidence derived from observational studies or case series, with strong recommendation, which may change when higher quality evidence becomes available.

Table 25. *Characteristics of published randomized trials of caudal epidural injections.*

Study/Methods	Participants	Intervention(s)	Outcome(s)	Result(s)	Conclusion(s) Short-term relief ≤ 6 mos Long-term relief > 6 mos
Dashfield et al 2005 (275) Prospective, randomized, double-blind trial	60 patients with a 6–18 months history of sciatica to either targeted epidural local anaesthetic and steroid placement with a spinal endoscope or caudal epidural local anaesthetic and steroid treatment.	Corticosteroid injection with a total of 10 mL of lidocaine 1% with 40 mg of triamcinolone Epiduroscopy group: delivery of the medication over the painful nerve root with 10 mL of lidocaine 1% with 40 mg of triamcinolone.	Assessments: 6 wks, 3 mos, and 6 mos . Outcome instruments: SF-MPQ and HAD.	Caudal group: significant improvements were found for descriptive pain at 6 mos; VAS at 6 wks, 3 mos, and 6 months; present pain intensity at 3 mos and 6 mos; anxiety at 6 wks, 3 mos, and 6 mos; and depression at 6 mos only.	Positive short-term relief. Long-term relief information not available
Matthews et al 1987 (277) Randomized, double-blind trial	57 pts with sciatica with a single root compression Experimental group: male/female: 19/4, median duration of pain: 4 wks. Control group: male/female: 24/10, median duration of pain: 4 wks.	Experimental: 20 mL bupivacaine 0.125% + 2 mL (80 mg) methylprednisolone acetate (n=23). Control: 2 mL lignocaine (over the sacral hiatus or into a tender spot) (n=34) Frequency: fortnightly intervals, up to 3 times as needed.	Timing: 2 wks, 1, 3, 6, and 12 mos. Outcome measures: pain (recovered vs not recovered), range of movement, straight leg raising, neurologic examination.	There was no significant difference between experimental and control group with short-term relief (67% vs 56%). After 3 mos, pts in experimental group reported significantly more pain-free than in control group.	Negative short-term and positive long-term relief
Breivik et al 1976 (283) Randomized, double-blind trial	35 pts with incapacitating chronic low back pain and sciatica. Diagnosis based on radiculopathy: arachnoiditis (n=8), no abnormality (n=11), inconclusive findings (n=5). Duration: several mos to several yrs.	Caudal epidural injection: Experimental: 20 mL bupivacaine 0.25% with 80 mg depomethylprednisone (n=16) Placebo: 20 mL bupivacaine 0.25% followed by 100 mL saline (n=19). Frequency: up to three injections at weekly intervals.	Outcome measures: 1. Pain relief 2. Objective improvement: sensation, Lasègue's test, paresis, spinal reflexes, and sphincter disorders.	56% of the pts reported considerable pain relief in experimental group compared to 26% of the pts in the placebo group.	Positive short-term relief. Long-term relief information not available
Bush and Hillier 1991 (284) Randomized, double-blind trial	23 pts with lumbar nerve root compromise randomized into 2 groups.	Experimental: 25 mL: 80 mg triamcinolone acetonide + 0.5% procaine hydrochloride (n=12); Control: 25 mL normal saline (n=11). Frequency: two caudal injections in 2 wks.	Timing: 4 wks and at 1 year. Outcome measures: 1. Effect on lifestyle; 2. Back and leg pain; 3. Angle of positive SLR.	Significantly better results with pain and straight leg raising in experimental group in short-term. Pain not significantly different but straight leg raise significantly better for long-term relief.	Positive short-term and long-term relief
Hesla and Breivik 1979 (288) Randomized, double-blind trial with crossover design	69 pts with sciatica. 36 of 69 previously been operated on for herniated disc. 26 patients without previous back surgery, were treated in a double-blind trial by 3 lumbar epidural injections.	26 patients without previous back surgery treated in a double-blind trial by 3 lumbar epidural injections of bupivacaine and depomethylprednisolone 80 mg and a placebo intramuscular injection, or lumbar epidural bupivacaine and depomethylprednisolone given intramuscularly.	Timing: not mentioned. Outcome measures: significant improvement to return to work or to be retrained for another occupation.	34 of the 58 pts (59%) receiving caudal epidural injections of bupivacaine and depomethylprednisolone showed significant improvement. 50% of previously operated patients and 70-80% of patients without previous back surgery obtained significant pain relief.	Positive short-term and long-term relief.
Revel et al 1996 (285) Randomized trial	60 postlumbar laminectomy pts with chronic low back pain.	Forceful caudal injection: Experimental: 125 mg of prednisolone acetate with 40 mL of normal saline. Control: 125 mg of prednisolone in the control group.	Timing: 6 mos. Outcome measures: pain relief.	The proportion of pts relieved of sciatica was 49% in the forceful injection group compared to 19% in the control group with significant difference.	Positive short-term relief. No long-term data available

Adapted and modified from Abdi S et al. Epidural steroids in the management of chronic spinal pain: A systematic review. *Pain Physician* 2007; 10:185-212 (56).

Table 26. *Results of randomized trials of effectiveness of caudal epidural steroid injections.*

Study	Study Characteristics	Methodological Quality Scoring		Participants	Pain Relief				Results	
		ACOEM Score x 9.1	Reassessment Score		≤ 3 mos	3 mos	6 mos	12 mos	Short-term relief ≤ 6 months	Long-term relief > 6 months
Dashfield et al 2005 (275)*	RA, DB	77.35	50	Caudal=30 Endoscopy=30	SI	SI	SI	NA	P	NA
Mathews et al 1987 (277)*	RA, DB	40.95	62	C=34 T=23	56% vs 67%	SI	SI	SI	N	P
Breivik et al 1976 (283)	RA, DB	NUA	68	C=19 T=16	25% vs 63%	20% vs 50%	20% vs 50%	NA	P	NA
Hesla and Breivik 1979 (288)	RA, DB	NUA	58	69 patients: crossover design	NA	77% vs 29%	59% vs 25%	59% vs 25%	P	P
Revel et al 1996 (285)	RA	NUA	62	Forceful injection=29 Regular=31	NA	NA	49% vs 19%	NA	P	NA

* Indicates use in ACOEM guidelines.

RA = randomized; DB = double blind; NUA = not utilized in analysis by authors of ACOEM guidelines; *C = control; T = treatment; NA = not available; SI = significant improvement; vs = versus; P = positive; N = negative;*

Adapted and modified from Boswell MV et al. Interventional techniques: Evidence-based practice guidelines in the management of chronic spinal pain. *Pain Physician* 2007; 10:7-111 (1).

Interlaminar Epidural Injections

In spite of the fact that interlaminar epidurals are controversial, the ACOEM guidelines not only have not performed an appropriate evidence search, synthesis, or incorporation of this evidence into their guidelines, they also have not evaluated the studies separately and did not utilize any evidence in the cervical region. Thus, multiple systematic reviews (50-52,56,65,66,264,265) provided conflicting opinions. However, most of the systematic reviews (50-53,264,265) utilized combined caudal and interlaminar epidural steroid injections in their evidence synthesis and the systematic reviews.

Poor Selection Criteria and Evidence Synthesis by the ACOEM Guidelines

The ACOEM guidelines utilized 8 studies (267, 269,271,272,276,278,279,292) in their descriptions. In contrast, Boswell et al (1) and Abdi et al (56) utilized 11 studies either on disc herniation, sciatica, or radiculopathy in the lumbar spine for evidence synthesis (267, 270, 271,279,284,292,293). However, of these 11 studies, only 4 were included in the ACOEM guidelines (267,271,279,292).

Evidence from Systematic Reviews

Boswell et al (1) and Abdi et al (56) also utilized 2 randomized evaluations for cervical disc herniation with radiculitis (294,295). They (1,56) identified 2 reports (267,269) separately published with the results of one study. In contrast, the ACOEM guidelines used them as separate studies. Further, none of the randomized evaluations were performed to manage low back pain without radiculopathy. Other studies included in both evaluations (270,271,279) were judged to be negative by both guidelines. The studies not included by the ACOEM guidelines were those by Rogers et al (296), Snoek et al (297), and Ridley et al (298), which were all negative. On the contrary, a study by Dilke et al (299) provided positive evidence for short-term with no long-term follow-up.

Table 27. *Methodological assessment of randomized clinical trials evaluating the effectiveness of lumbar and cervical interlaminar epidural injections.*

CRITERION		WEIGHTED SCORE	Arden et al (267)	Carette et al (270)	Cuckler et al (279)	Wilson-MacDonald et al (271)	Snoek et al (297)	Ridley et al (298)	Castagnera et al (294)	Stav et al (295)
Study population										
A	Homogeneity	2	2	2	2	2	2	2	2	2
B	Comparability of relevant baseline characteristics	5	5	5	4	5	3	4	5	5
C	Randomization procedure adequate	4	4	4	4	4	4	2	4	4
D	Drop-outs described for each study group separately	3	3	3	3	3	3	—	3	3
E	≤ 20% loss for follow-up	2	—	—	2	2	2	2	2	—
	≤ 10% loss for follow-up	2	—	—	2	2	2	—	2	—
F	> 50 subject in the smallest group	8	8	8	—	—	—	—	—	—
	> 100 subjects in the smallest group	9	9	—	—	—	—	—	—	—
Interventions										
G	Interventions included in protocol and described	10	10	10	10	10	10	10	10	10
H	Pragmatic study	5	—	—	5	—	—	—	5	—
I	Co-interventions avoided	5	—	—	—	—	5	—	—	—
J	Placebo-controlled	5	5	5	—	—	5	5	—	5
Effect										
K	Patients blinded	5	5	5	3	5	3	3	5	5
L	Outcome measures relevant	10	10	10	2	10	8	4	4	5
M	Blinded outcome assessments	10	10	10	10	10	10	10	—	—
N	Follow-up period adequate	5	5	5	5	5	5	5	5	5
Data-presentation and analysis										
O	Intention-to-treat analysis	5	5	5	5	5	5	—	5	5
P	Frequencies of most important outcomes presented for each treatment group	5	5	5	5	5	5	—	5	5
TOTAL SCORE		**100**	**86**	**77**	**62**	**68**	**72**	**47**	**57**	**54**

Methodological criteria and scoring adapted from Koes BW et al. Efficacy of epidural steroid injections for low-back pain and sciatica: A systematic review of randomized clinical trials. *Pain* 1995; 63:279-288 (51).

However, for cervical interlaminar epidurals, both studies by Castagnera et al (294) and Stav et al (295) showed positive results for both short-term and long-term relief.

Reassessment

Even though interlaminar epidurals have been shown consistently to be negative in systematic reviews, reassessment of the evaluation was undertaken.

Methodologic Quality Assessment

Methodologic quality assessment of the studies evaluating interlaminar epidural injections included in this evaluation are illustrated in Table 27. The results of methodologic assessment showed scores ranging from 47% to 86%.

Of the 6 studies meeting inclusion criteria, only one study by Ridley et al (298) scored below 50. All the other studies scored between 62 and 86 in evaluation of lumbar interlaminar epidural injections, as shown in Table 27. Of the 2 studies (294,295) meeting inclusion criteria for cervical interlaminar epidural steroid injections, both of them scored above 50 scores of with 54 (295) and 57 (294). All except for one study (298) had long-term results available. The study with lack of long-term results was by Ridley et al (298) with a score of 47 for lumbar interlaminar epidural injection.

Study Characteristics

Study characteristics of cervical and lumbar interlaminar epidural steroid injections are shown in Tables 28 and 29.

Results

The results of this evaluation showed negative evidence for lumbar interlaminar epidural steroid injections for long-term relief (Table 30). However, both the cervical studies showed positive results for cervical interlaminar epidural steroid injections (Table 30).

Level of Evidence

The evidence for cervical interlaminar epidural steroid injections is strong (A) based on the ACOEM criteria (Table 5) (33). Quality criteria of evidence developed by AHRQ USPSTF (Table 3) (21) places. This evidence into Group I.

The evidence for lumbar interlaminar epidural steroid injections based on randomized trials is insufficient (1), basedased on ACOEM criteria (33), the evidence is II-3 based on AHRQ USPSTF criteria (21).

Recommendations

Based on Guyatt et al's criteria (19), the recommendation for cervical interlaminar epidurals is 1A or 1B/strong recommendation, high or moderate quality

Table 28. *Characteristics of published randomized trials of cervical interlaminar epidural injections.*

Study/Methods	Participants	Intervention(s)	Outcome(s)	Result(s)	Conclusion(s) Short-term relief ≤ 6 mos Long-term relief > 6 mos
Castagnera et al 1994 (294) Randomized trial	14 patients: local anesthetic and steroid. 10 patients: local anesthetic, steroid + morphine sulfate.	I. 0.5% lidocaine + triamcinolone acetonide. II. Local anesthetic + steroid + 2.5 mg of morphine sulfate.	Timing: 1 month, 3 mos, and 12 mos. Outcome measures: pain relief.	The success rate was 79% vs. 80% in group I and II. Overall, initial success rate was 96%, 75% at 1 month, 79% at 3 mos, 6 mos, and 12 mos.	Positive short-term and long-term relief
Stav et al 1993 (295) Randomized trial	Experimental: 25 patients. Control: 17 patients.	Experimental: epidural steroid and lidocaine injections Control: steroid and lidocaine injections into the posterior neck muscles	Timing: 1 week and 1 year. Outcome measures: pain relief, change in range of motion, reduction of daily dose of analgesics, return to work.	One week improvement 36% vs 76%; One year improvement 12% vs 68%.	Positive short-term and long-term relief

Adapted and modified from Abdi S et al. Epidural steroids in the management of chronic spinal pain: A systematic review. *Pain Physician* 2007; 10:185-212 (56).

Table 29. *Characteristics of published randomized trials of lumbar interlaminar epidural injections.*

Study/Methods	Participants	Intervention(s)	Outcome(s)	Result(s)	Conclusion(s) Short-term relief ≤ 6 mos Long-term relief > 6 mos
Wilson-McDonald et al 2005 (271) Randomized, controlled trial	93 pts with MRI evidence of a disc prolapse, spinal stenosis, or a combination. Pts had lumbosacral nerve root pain which had not resolved within 6 wks minimum .	Experimental: epidural injection of bupivacaine 0.5% (40 mg) with methylprednisone 80 mg. Control: intramuscular injection of 0.5% (40 mg) bupivacaine with 80 mg methylprednisone.	Timing: 6 wks, 24 mos. Outcome measures: Oswestry Disability index, pain relief.	In the first 5 wks after epidural injection a useful improvement in nerve root symptoms was seen.	Positive short- term and negative long-term relief
Arden et al 2005 (267) Double-blind, randomized placebo controlled: TRIM	228 pts with unilateral sciatica .	Experimental: triamcinolone 80 mg and 10 ml of 0.25% bupivacaine Control: interspinous injection with 2 mL of normal saline.	Timing: 3, 6, 12, 26, and 52 weeks. Outcome measures: Oswestry disability index, Likert scale, SF-36, VAS.	Lumbar epidural steroid injection produced a statistically significant improvement in function over placebo in 3 wks. By 6 wks, benefit lost.	Positive short-term and negative long-term relief
Carette et al 1997 (270) Randomized, double-blind trial	158 pts with sciatica due to a herniated nucleus pulposus. Treatment group: 78 Placebo group: 80.	Experimental: methylprednisolone acetate (80 mg and 8 mL of isotonic saline) Control: isotonic saline 1 mL Frequency: 3 epidural injections 3 wks apart.	Timing: 6 wks, 3 mos, 12 mos Outcome measures: need for surgery Oswestry Disability scores.	Significant improvement was seen in leg pain in the methylprednisolone group after 6 weeks, with no difference after 3 and 12 mos.	Positive short-term and negative long-term relief
Snoek et al 1977 (297) Randomized trial	51 pts with lumbar root compression documented by neurological deficit and a concordant abnormality noted on myelography. Experimental: 27 Control: 24.	Experimental: 80 mg of methylprednisolone (2 mL). Control: 2 mL of normal saline Frequency: single injection.	Timing: 3 days and an average of 14 mos. Outcome measures: Pain, sciatic nerve stretch tolerance.	No statistically significant differences were noted in either group.	Negative short-term and long-term relief
Cuckler et al 1985 (279) Randomized, double-blind trial	73 pts with back pain due to either acute herniated nucleus pulposus or spinal stenosis of > 6 mos. Experimental: 42 Control: 3.1	Experimental: 80 mg (2 mL) of methylprednisolone + 5 mL of procaine 1%. Control group: 2 mL saline + 5 mL of procaine 1%.	Timing: 24 hrs and an average of 20 mos. Outcome measures: subjective improvement, need for surgery.	There was no significant short-term or long-term improvements between both groups.	Negative short-term and long-term relief
Ridley et al 1988 (298) Randomized trial	35 pts with low back pain and sciatica of mean duration approximately 8 mos. Experimental: 19 Control: 16.	Experimental: 10 mL of saline + 80 mg of methylprednisolone (n=19). Control: saline 2 mL, interspinous ligament (n=16).	Timing: 1 wk, 2 wks, 3 mos, and 6 mos. Outcome measures: pain control improvement in straight leg raising.	90% of the pts in the treated group compared to 19% in the control group showed improvement at 1 wk, 2 wks, and 12 wks. By 24 wks, relief deteriorated to pretreatment levels.	Positive short-term relief. Long-term results not available.

Adapted and modified from Abdi S et al. Epidural steroids in the management of chronic spinal pain: A systematic review. *Pain Physician* 2007; 10:185-212 (56).

Table 30. *Results of randomized trials of effectiveness of cervical and lumbar interlaminar epidural steroid injections.*

Study	Study Characteristics	Methodological Quality Scoring		Participants	Pain Relief				Results	
		ACOEM Score x 9.1	Reassessment Score		≤ 3 mos	3 mos	6 mos	12 mos	Short-term relief ≤ 6 mos	Long-term relief > 6 mos
Cervical										
Castagnera et al 1994 (294)	RA	NUA	57	Local anesthetic with steroids =14 Local anesthetic with steroids and morphine =10	75%	79%	79%	79%	P	P
Stav et al 1993 (295)	RA	NUA	54	C=17 T=25	36% vs 76%	12% vs 68%	12% vs 68%	12% vs 68%	P	P
Lumbar										
Arden et al 2005 (267)*	RA, DB, PC	86.45	86	228	75%	NSD	NSD	NSD	P	N
Carette et al 1997 (270)*	RA, DB, PC	77.35	77	C=80 T=78	SIT	NSD	NSD	NSD	P	N
Cuckler et al 1985 (279)*	RA, DB	44	62	C=31 T=42	NSD	NSD	NSD	NSD	N	N
Wilson-MacDonald et al 2005 (271)*	RA	63.7	68	93	SI	NSD	NSD	NSD	P	N
Snoek et al 1977 (297)	RA	NUA	72	C=24 T=27	NSD	NSD	NSD	NSD	N	N
Ridley et al 1988 (298)	RA	NUA	47	C=16 T=19	19% vs 90%	19% vs 90%	NSD	NA	P	N

* Indicates use in ACOEM guidelines.

RA = randomized; DB = double blind; PC = placebo controlled; C = control; T = treatment; SIT = significant improvement in treatment group; NSD = no significant difference; SI = significant improvement; vs = versus; P = positive; N = negative; NA = not available; NUA = not utilized in analysis by authors of ACOEM guidelines

evidence, with benefits clearly outweighing the risks and burdens, with evidence derived from randomized controlled trials with or without important limitations or exceptionally strong evidence from observational studies, the recommendation applying to most patients in most circumstances without reservation.

For lumbar interlaminar epidural steroids, based on the ACOEM criteria, the evidence is insufficient (1). Further, without any positive results with lumbar interlaminar epidural injections in randomized trials, the recommendations would have to be based on observational studies, which were not evaluated.

Consequently, based on Guyatt et al's (19) recommendations, the recommendations will fall between 2A to 2C with weak or very weak recommendation with best action differing depending on circumstances or patients' or societal values or other alternatives may be equally reasonable.

Transforaminal Epidural Injections

Poor Selection Criteria and Evidence Synthesis by the ACOEM Guidelines

Transforaminal epidurals were also given a negative recommendation by the ACOEM guidelines. They reviewed 2 randomized controlled trials to evaluate effectiveness of transforaminal epidural injections (268,274). Ng et al (274) compared a single transforaminal injection either with bupivacaine or bupivacaine and methylprednisolone in 86 patients with chronic radicular pain. They concluded that periradicular infiltration is a safe and simple procedure to provide short-term pain relief and that the diagnosis of nerve root pain can also be confirmed with a positive response to this procedure. Improvement was noted in both groups of patients. Thus, the corticosteroid did not produce a treatment effect or an additional benefit for patients with chronic radicular pain. ACOEM considered that it was important that data were not given on the effects at less than 6 weeks.

A second randomized controlled trial compared bupivacaine and methylprednisolone with isotonic sodium chloride solution for 160 patients with sciatica (268). The authors of this study (268) concluded both treatments had induced clinical improvements. However, periradicular infiltration with a combination of bupivacaine and methylprednisolone was superior to saline injection for leg pain, straight leg raising, and lumbar flexion (in addition to patient satisfaction), according to findings at 2 weeks but not at later follow-up assessments.

Systematic Reviews and Contrasting Evidence

Boswell et al (1) and Abdi et al (56) utilized multiple other studies and arrived at different conclusions. Four systematic reviews (53,62,63,300) and multiple guidelines (1,82-84,88) showed moderate evidence for lumbar transforaminal epidural injections.

Boswell et al (1) and Abdi et al (56) in their evidence synthesis identified 11 randomized controlled trials and 15 observational reports. Of the 11 randomized controlled trials (268,270,276,301-308), they included 8 trials in the evidence synthesis (268,276,301-306), of which 6 evaluated effectiveness of lumbar disc herniation and radiculopathy (268,276,301-302,305,306), showing positive results in 4 of the 6, with 2 negative studies (268,274). The seventh trial (303) studied the effectiveness in post surgery syndrome and yielded negative results. Further, 2 studies were published as 4 reports (268,270,301,302). The authors of the ACOEM guidelines chose only 2 negative studies (270,276) and neglected to review the follow-up publication by Karppinen et al (309) which yielded positive results in a select group of patients. What is more important is that the ACOEM guidelines did not include the studies of Riew et al (301,302) with long-term follow-up, Devulder et al (303), Vad et al (305), and Thomas et al (306).

Reassessment

Based on the inadequate synthesis performed by the ACOEM guidelines, a reassessment was performed with inclusion of multiple studies which were not considered in the ACOEM guidelines.

Methodologic Quality Assessment

Table 31 illustrates methodologic quality assessment of all the randomized trials. The quality assessment criteria scores ranged from 39% to 81%. Four of the 5 studies met inclusion criteria after removal of the duplications. Only one study by Devulder et al (303) scored 39. All other studies scored above 50, ranging from 58 to 81.

Study Characteristics

Study characteristics are illustrated in Table 32.

Results

Results of randomized trials of effectiveness of lumbar transforaminal epidural steroid injections are illustrated in Table 33.

The results showed positive results in 4 of the 4 studies, which met inclusion criteria (268,301,302,305,306,309) for short-term relief of 6 months or less. However, for long-term relief, 3 studies (268,301,302,305,309) were available and 2 of them (301,302,305) showed positive results. Further, Karrpinen et al (309) of randomized controlled trial (268) showed that in case of contained herniations, the steroid injection produced significant treatment

Table 31. Methodological assessment of randomized clinical trials evaluating the effectiveness of lumbar transforaminal epidural injections.

Criterion		WEIGHTED SCORE	Riew et al (301,302)	Devulder et al (303)	Vad et al (305)	Thomas et al (306)	Karppinen et al (268,309)
Study population							
A	Homogeneity	2	2	2	2	2	2
B	Comparability of relevant baseline characteristics	5	5	5	3	3	5
C	Randomization procedure adequate	4	4	4	1	4	4
D	Drop-outs described for each study group separately	3	3	3	3	3	3
E	≤ 20% loss for follow-up	2	2	2	2	2	2
	≤ 10% loss for follow-up	2	2	2	2	2	2
F	> 50 subject in the smallest group	8	—	—	—	—	8
	> 100 subjects in the smallest group	9	—	—	—	—	—
Interventions							
G	Interventions included in protocol and described	10	10	10	10	10	10
H	Pragmatic study	5	5	5	5	—	—
I	Co-interventions avoided	5	—	—	—	—	—
J	Placebo-controlled	5	—	—	—	5	5
Effect							
K	Patients blinded	5	5	1	—	5	5
L	Outcome measures relevant	10	10	2	10	10	10
M	Blinded outcome assessments	10	5	1	5	10	10
N	Follow-up period adequate	5	5	2	5	2	5
Data-presentation and analysis							
O	Intention-to-treat analysis	5	5	—	5	5	5
P	Frequencies of most important outcomes presented for each treatment group	5	5	—	5	5	5
	TOTAL SCORE	**100**	**68**	**39**	**58**	**68**	**81**

Methodological criteria and scoring adapted from Koes BW et al. Efficacy of epidural steroid injections for low-back pain and sciatica: A systematic review of randomized clinical trials. *Pain* 1995; 63:279-288 (51).

effect, not only in short-term, but by 1-year steroids seemed to have prevented operations for contained herniations, costing $12,666 less per responder in the steroid group ($P \leq 0.01$). Thus, the evidence may be considered positive in a select group of patients for long-term relief with contained disc herniations even in Karrpinen's studies (268,309).

Level of Evidence

Based on the available evidence as shown in Table 33, utilizing only randomized trials and long-term relief of ≥ 6 months, the evidence is positive in 2 studies (301,302,305) and negative in one study (268,309), with results not available in one study (306). Further, Karppinen et al in their subgroup analysis (309) of the randomized trail (268) showed significantly positive

Table 32. *Details of randomized trials studying the effectiveness of lumbar transforaminal epidural steroid injections.*

Study/Methods	Participants	Intervention(s)	Outcome(s)	Result(s)	Conclusion(s) Short-term relief ≤6 mos Long-term relief > 6 mos
Karppinen et al 2001 (268,309) Randomized, double-blind trial	160 consecutive, eligible pts with sciatica with unilateral symptoms of 1 to 6 mos duration. None of the pts had undergone surgery.	Experimental: local anesthetic and methylprednisolone. Control: normal saline.	Timing: 2 wks, 3 mos, 6 mos, and 1 yr Outcome measures: Pain relieffuture surgery, Nottingham Health Profile, cost effectiveness.	Steroid injection produced significant treatment effects and short-term improvement. By 1-year, steroid seemed to have prevented operations for contained herniations, costing $12,666 less per responded in the steroid group (P ≤ 0.01).	Positive short-term relief and negative long-term relief. For contained herniations and lesions at L3-L4-L5, steroid treatment also prevented surgery for contained herniations. However, steroid was counter effective for extrusions.
Riew et al 2000/2006 (301,302) Prospective, randomized, controlled, double-blind study	55 pts with lumbar disc herniations or spinal stenosis referred for surgical evaluation. 28 pts in experimental group (bupivacaine and betamethasone) and 27 pts in control group (bupivacaine only).	Experimental: transforaminal nerve root or epidural steroid injection with 1 mL of 0.25% bupivacaine and 6 mg of betamethasone Control: 1 mL of 0.25% bupivacaine.	Initial outcomes were evaluated at 1 year. Injection was considered as a failure if the patient opted for operative treatment. North American Spine Society questionnaire also used.	20 of 28 patients in steroid group, 9 of 27 patients in control group had no surgery at 1 year. 17 of the 21 pts still had successful results with no operative intervention after 5 yrs.	Positive short-term and long-term relief.
Vad et al 2002 (305) Prospective, randomized trials	Patients with leg pain, with documented herniated nucleus pulposus or manifested clinical signs such as radicular pain with lumbar radiculopathy.	Experimental: betamethasone 9 mg, and 2% preservative-free Xylocaine (1.5 mL) per level. Control: trigger point injections.	Timing: 3 wks, 6 wks, 3 mos, 6 mos, and 12 mos. Outcome measures: Roland-Morris score, visual numeric score, finger-to-floor distance, patient satisfaction score.	Group receiving transforaminal epidural steroid injections had 84% success rate compared with 48% for group receiving trigger point injections.	Positive short-term and long-term relief.
Thomas et al 2003 (306) Randomized, controlled trials	Thirty-one pts (18 females, 13 males) with discal radicular pain of less than 3 mos duration.	Pts were consecutively randomized to receive either radio-guided transforaminal or blindly performed interspinous epidural corticosteroid injections.	Post-treatment outcome was evaluated clinically at 6 and 30 days, and 6 mos. Outcome measures: pain, functional status.	At day 30 and 6 mos, pain relief, daily activities, work, leisure activities, anxiety, and depression were better in transforaminal group.	Positive short-term relief. There was no long-term follow-up available.

Adapted and modified from Abdi S et al. Epidural steroids in the management of chronic spinal pain: A systematic review. *Pain Physician* 2007; 10:185-212 (56).

results for contained herniations with lesions at L3-L4-L5 at 1-year. The study by Devulder et al (303) with a methodological quality score of 39 was not utilized in the analysis and there were no long-term results available in the study.

Based on the ACOEM guidelines (33), the level of evidence is A with strong evidence base with 2 of the 3 positive studies.

Based on the quality of evidence developed by AHRQ USPSTF (Table 3) (21) the evidence is Level I.

Recommendations

Based on Guyatt et al's (19) criteria, the recommendation is 1A strong recommendation with high quality evidence with benefits clearly outweighing the risks, evidence derived from randomized controlled trials, resulting in a strong recommendation applying to most patients in most circumstances without reservation in managing disc herniation and radiculitis.

Table 33. *Results of randomized trials of effectiveness of lumbar transforaminal epidural injections.*

Study	Study Characteristics	Methodological Quality Scoring		Participants	Pain Relief				Results	
		ACOEM Score x 9.1	Reassessment Score		≤ 3 mos	3 mos	6 mos	12 mos	Short-term relief ≤ 6 mos	Long-term relief > 6 mos
Karppinen et al 2001/2001 (268*,309)	RA, DB	86.45	81	C = 80 T = 80	SICH	SICH	NSI	NSI	P	N
Riew et al 2000/2006 (301,302)	P, RA, DB	NUA	68	55	33% vs 77%	33% vs 77%	33% vs 77%	33% vs 77%	P	P
Vad et al 2002 (305)	RA	NUA	58	48	48% vs 84%	8% vs 84%	8% vs 84%	8% vs 84%	P	P
Thomas et al 2003 (306)	RA	NUA	68	C = 15 T = 16	SI	SI	SI	NA	P	NA

* Indicates use in ACOEM guidelines.
P = prospective; RA = randomized; DB = double blind; NUA = not utilized in analysis by authors of ACOEM guidelines; *C = control*; *T = treatment;* SICH = significant improvement in contained disc herniation; *SI = significant improvement; NSI = no significant improvement; vs = versus*; *NA = not available; P = positive; N = negative.*

Adapted and modified from Boswell MV et al. Interventional techniques: Evidence-based practice guidelines in the management of chronic spinal pain. *Pain Physician* 2007; 10:7-111 (1).

Sacroiliac Joint Interventions

The ACOEM guidelines (33) state that sacroiliac joints are believed to cause a minority of chronic low back pain cases with estimates ranging from 10% to 26.6%. They (33) admit that the most commonly performed interventions are sacroiliac joint injections either with or without fluoroscopic or other imaging guidance. They conclude that, the diagnostic precision of these injections is likely limited by factors that include the inability to inject the joint directly without fluoroscopic or other imaging, as well as the infiltration and diffusion of medication into surrounding tissues that could potentially be pain generators. Consequently, they recommend sacroiliac joint corticosteroid injections as a treatment option for patients with a specific known cause of sacroiliitis (i.e., proven rheumatologic inflammatory arthritis involving sacroiliac joints). However, the ACOEM guidelines do not recommend sacroiliac joint injections for acute low back pain, including low back pain thought to be sacroiliac joint related. There is no comment with regards to chronic sacroiliac joint pain.

Poor Selection Criteria and Evidence Synthesis by the ACOEM Guidelines

The ACOEM guidelines based their rationale for recommendation on 4 randomized controlled trials, even though 5 systematic reviews and one guideline were reviewed in the appendix section. Two of the studies included are those of Luukkainen et al (310,311). Luukkainen et al (310,311) reported their findings in 1999 and 2002 with periarticular corticosteroid injection of the sacroiliac joint in patients with chronic low back pain. The ACOEM guidelines report that there was no indication of fluoroscopic guidance. In both studies, they reported improvement in patients with clinical sacroiliitis with seronegative spondyloarthropathy. The ACOEM guidelines also utilized Klein et al (312) as a moderate-quality randomized controlled trial comparing prolotherapy injections with placebo. Baseline treatments after enrollment were not standardized and included injections of triamcinolone and back manipulations facilitated by injections of local anesthetic (33). Both groups improved markedly with improvements greater in the treatment versus the

Table 34. *Methodological assessment and scoring of diagnositc sacroiliac joint injection clinical trials.*

CRITERION	Weighted Score	Maigne et al (314)	Manchikanti et al (126)	Irwin et al (315)
1. Study Population				
• Subjects similar to populations in which the test would be used and with a similar spectrum of disease	30	30	30	30
2. Adequate Description of Test				
• Details of test and its administration sufficient to allow for replication of study.	15	15	15	15
3. Appropriate Reference Standard				
• Appropriate reference standard (gold standard) used for comparison	10	10	10	10
• Reference standard reproducible	10	10	10	10
4. Blinded Comparison of Test				
• Evaluation of test without knowledge of disease status, if possible	10	—	—	—
• Independent, blind interpretation of test and reference	10	—	—	—
5. Avoidance of Verification Bias				
• Decision to perform reference standard not dependent on results of test under study	15	15	15	15
TOTAL SCORE	100	80	80	80

Methodological criteria and scoring adapted from West S et al. Systems to Rate the Strength of Scientific Evidence, Evidence Report, Technology Assessment No. 47. AHRQ Publication No. 02-E016 (47).

placebo group, including pain measurements and disability. However, this study evaluated low back pain, rather than sacroiliac joint pain. The final randomized controlled trial included in the evaluation of the ACOEM guidelines was of Maugars et al (313). This was a study of 10 patients with spondyloarthropathy.

The literature has shown that sacroiliac joint pain may be managed by intraarticular injections and neurolysis of the sacroiliac joint. The effectiveness of intraarticular sacroiliac joint injections was evaluated in 2 systematic reviews (57,64), and multiple guidelines (1,82-84); however, all of them have concluded that there was no significant evidence for therapeutic intraarticular injections. For radiofrequency neurotomy there were no randomized evaluations available for inclusion criteria.

Validity of Diagnosis

The published evidence is moderate for the diagnosis of sacroiliac joint pain utilizing controlled, comparative local anesthetic blocks (1,57,64,126,314,315). There are no precise or definite historical, physical, or radiological features to provide accurate diagnosis of sacroiliac joint pain (1,57,64,126,215,314-346). Even then, many authors (323-325,337,338) have advocated provocative maneuvers, which may enter into the differential diagnosis of sacroiliac joint pain. Accuracy of sacroiliac joint blocks has been established by the study of face validity and construct validity. Controlled, comparative local anesthetic blocks established a false-positive rate of single, uncontrolled, sacroiliac joint injections of 20% to 22% (126,314). False-positive responses may occur with extravasation of an anesthetic agent out of the joint due to defects in the joint capsule (345).

Table 35. Descriptive characteristic of diagnostic studies evaluating prevalence and false-positive rates of sacroiliac joint pain.

Study	Participants	Objective(s)	Interventions(s)	Result(s)
Maigne et al 1996 (314)	54 patients aged 18-75 with chronic unilateral LBP with or without radiation to the posterior thigh for > 50 days (median 4.2 months). Patients had failed epidural or lumbar facet injections.	To determine the prevalence of sacroiliac joint pain in a selected population of patients with low back pain and assess certain pain provocation tests.	Successful blockade of the sacroiliac joint in 54 patients. A screening block was done with 2% lidocaine and a confirmatory block was performed with bupivacaine 0.5% > 75% relief was considered a positive block.	Prevalence = 18.5% False-positive rate = 20%
Manchikanti et al 2001 (126)	120 patients (age 18-90) presenting to the clinic with > 6 months of low back pain and no structural basis for the pain by radiographic imaging. 20 patients were evaluated for SI joint pain.	To determine the frequency of various structures responsible for low back pain.	All patients had facet blocks. Nonresponders who fit criteria had double injection SIJ blocks. The screening block was done with 2% lidocaine and the confirmatory block was performed using 0.5% bupivacaine.	The incidence of SIJ pain was 2% of the overall sample and 10% of those suspected to have SIJ pain. The false-positive rate was 22%.
Irwin et al 2007 (315)	158 patients underwent sacroiliac joint injections with average symptoms duration of 34 months. Patients failed conservative modalities prior to injection therapy.	To evaluate prevalence and correlation between age, gender, and body mass index by dual comparative local anesthetic blocks.	The fluoroscopically guided contrast-enhanced sacroiliac joint injections were performed initially with 2 mL of 2% lidocaine for the first injection, followed by 2 mL of 0.25% bupivacaine, a local anesthetic, for the confirmatory injection. A patient was required to have at least 70% reduction of familiar painful symptoms after the initial injection for 3 or 4 hours for positive response.	26.6% were found to have sacroiliac joint pain by dual injections.

Adapted and modified from Hansen HC et al. Sacroiliac joint interventions: A systematic review. *Pain Physician* 2007; 10: 165-184 (60).

Further, false-negative results may occur from faulty needle placement, intravascular injection, or the inability of the local anesthetic to reach the painful portion of the joint due to loculations (57,64,316-318).

Reassessment

Due to inappropriate assessment by the ACOEM guideline synthesis, specifically for diagnostic facet joint nerve blocks, methodological quality assessment was performed for diagnostic facet joint nerve blocks. There were no randomized trials for therapeutic sacroiliac joint interventions either intraarticular or radiofrequency neurotomy.

Methodologic Quality Assessment

Table 34 illustrates the methodological quality assessment criteria. Methodologic quality criteria assessment showed scores of 80 for all 3 studies (126,314,315). Thus, all the studies met inclusion criteria for diagnostic studies based on AHRQ criteria (47).

Results

Descriptive characteristics of the studies included for diagnostic assessment are illustrated in Table 35 along with the results. As shown in Table 35, the prevalence of sacroiliac joint pain varied from 10% to 26.6% (126,314,315). Further, the results also showed a false-positive rate of 20% or 22%.

Level of Evidence

The results based on this re-evaluation of the evidence for sacroiliac joints shows moderate evidence for diagnostic sacroiliac joint blocks based on ACOEM guidelines. Based on, AHRQ USPSTF evidence base (Table 3) (21) the evidence for diagnostic sacroiliac joint blocks is Level I.

There is no level of evidence assessed or derived from this evaluation for therapeutic sacroiliac joint interventions.

Recommendations

Utilizing methodologic assessment quality criteria for diagnostic assessment (47) and the evidence based on Guyatt et al's criteria (19) the recommendation is 1A or 1B/strong recommendation with high or moderate-quality evidence. Further, strong recommendation can apply to most patients in most circumstances without reservation for diagnosis. Based on the present reassessment, no recommendation could be derived for therapeutic interventions due to lack of evidence from randomized trials and rather limited evidence from observational studies.

Percutaneous Adhesiolysis

Adhesiolysis was not recommended by the ACOEM guidelines for acute, subacute, or chronic low back pain, spinal stenosis, or radicular pain syndromes due to insufficient evidence (33).

Poor Selection Criteria and Evidence Synthesis by the ACOEM Guidelines

The rationale for the lack of ACOEM recommendation includes poorly conceived evidence. The ACOEM guidelines (33) state that adhesiolysis has been reported to show encouraging results in relatively small case studies and other uncontrolled or poorly controlled studies with a reference from 2001, a focused review article of spinal endoscopy (347). The authors also allege that there are no reported large scale, controlled clinical trials involving adhesiolysis and few existing quality studies are largely from the 2 small US cities (33). One of the studies has been labeled by the ACOEM authors with an incorrect study design (33,348), in that patients were "entered into a different study after they failed treatment" with a reference to a personal communication (349) which raised concerns in the minds of the ACOEM guidelines authors about selection bias, spectrum bias, and a potential uncontrolled confounder due to enrolling subjects into multiple studies. However, they quoted a wrong study (348), which was mentioned in the letter (349) and no such information was provided with regards to this study (350). The study mentioned was a different study (350), and the letter published in the appendix section (33) does not support the above claims.

Based on suboptimal methodology and inappropriate review of the evidence, the ACOEM authors have concluded that large scale, high-quality, multicenter studies with long-term follow-up are needed prior to consideration of this intervention for recommendation. Even then, they considered 3 high or moderate-quality randomized controlled trials incorporated into the analysis along with 5 systematic reviews, one guideline, and 2 low-quality studies referenced in the appendix. However, in this analysis they also combined spinal endoscopy and percutaneous adhesiolysis, 2 separate and distinct procedures (1,55,65,66,84,350-356).

The first randomized controlled trial they evaluated was that of Manchikanti et al (352); which they rated as a moderate-quality randomized controlled trial of 75 patients with chronic low back pain, comparing 3 treatment groups. Patients had chronic low back or lower extremity pain of at least 2 years, a minimum VAS of 6, no facet joint pain based on controlled, comparative local anesthetic blocks, and failed to respond to conservative treatment including epidural injections. Group I had no adhesiolysis, but received a local anesthetic injection with steroid and normal saline. Group II had adhesiolysis with local anesthetic, steroid, and normal saline. Group III had adhesiolysis, hypertonic saline injection ,and local anesthetic with steroids. The authors of this manuscript (352) concluded that "percutaneous adhesiolysis, with or without hypertonic saline neurolysis, is an effective treatment for low back pain and/or lower extremity pain (33)." The authors of the ACOEM guidelines claim that there were issues of unblinding in this trial (33). However, no documentation was provided to support the allegation.

The second study was also by Manchikanti et al (351), a preliminary publication in 2003, evaluating spinal endoscopic adhesiolysis. The authors of this manuscript (351) concluded that spinal endoscopic adhesiolysis with targeted injection of local anesthetic and steroid is an effective treatment in a significant number of patients without major adverse effects at 6-month follow-up. Authors of the ACOEM guidelines either purposefully excluded or were unable to perform their search for 1-year follow-up of the same study published in 2005 (354).

The third study used by ACOEM was of Veihelmann et al (355). The study is described as a moderate-quality randomized controlled trial comparing 52 patients receiving physiotherapy with 47 patients undergoing epidural neuroplasty, for 99 patients with chronic low back pain and sciatica based on disc protrusion/prolapse or failed back surgery on a short-term basis as well as at 12 months of follow-up. The diagnosis of sciatica was based on radicular pain and a positive MRI, with VAS scores suggesting slightly worse leg pain than low back pain (33). The authors of this manuscript (355) concluded that taking into account that the results of discectomy are not necessarily superior to conservative treatment, data shows, for the first time, that for patients with radicular pain due to disc protrusion and herniation or epidural fibrosis, epidural neuroplasty seems to be an effective safe alternative treatment (33). The authors (355) also concluded that at least 3 months after neuroplasty, it is superior in comparison to conservative treatment with physiotherapy. Nevertheless, they suggested that further prospective randomized double-blinded studies should be performed to prove the effectiveness of

epidural neuroplasty in comparison to placebo and in comparison to open discectomy procedures (355).

Systematic Reviews and Contrasting Evidence

The clinical effectiveness of percutaneous adhesiolysis was evaluated in 2 systematic reviews (55,65), one technology assessment (66), and multiple guidelines (1,82-84). The systematic reviews and guidelines (1,55,65) concluded that there is strong evidence in managing chronic low back and lower extremity pain in post-surgery syndrome with moderate evidence in managing low back and lower extremity pain secondary to disc herniation producing radiculopathy, whereas, the evidence was limited in managing back and/or lower extremity pain secondary to spinal stenosis with percutaneous adhesiolysis. In contrast, for spinal endoscopic adhesiolysis, the same authors (1,55,65) concluded that the evidence for spinal endoscopy is moderate for long-term relief (greater than 6 months), in managing chronic refractory low back and lower extremity pain secondary to post-lumbar surgery syndrome

Boswell et al (1) and Trescot et al (58) identified 14 relevant articles for percutaneous adhesiolysis with catheter including 4 randomized trials (352,355-357), 3 prospective evaluations (350,358,359), and 3 retrospective evaluations (348,360,361). They excluded 4 studies which failed to meet inclusion criteria. Two of the randomized studies (352,355) were also utilized in the ACOEM guidelines, but with a misinterpretation of the data. The other 2 trials (356,357) were not included in the ACOEM guidelines. The study by Heavner et al (356) was performed at an academic university medical center with extensive outcome evaluations, showing positive results with adhesiolysis performed in 59 patients with relief sustained in 49% of the patients after 1-year with one 3-day catheter based adhesiolysis procedure.

Reassessment

Due to multiple deficiencies and misconceptions of evaluation of percutaneous adhesiolysis by ACOEM, the reassessment was performed utilizing accurate information with expanded inclusion of multiple studies which were not included in the ACOEM guideline synthesis, even though they were published and available.

Methodologic Quality Assessment

Methodologic quality assessment of percutaneous adhesiolysis is illustrated in Table 36. Assessment included 3 studies of percutaneous adhesiolysis and one study of spinal endoscopic adhesiolysis (352,354-356). The quality assessment criteria ranged from 50 to 69.

Study Characteristics

Table 37 illustrates the study characteristics of all adhesiolysis studies with only one randomized study (354) being available for spinal endoscopic adhesiolysis. Dashfield et al's study (275) was performed in patients without surgical intervention, thus, the study was excluded here.

Results

Results are illustrated in Table 38 with all 3 studies in percutaneous adhesiolysis showing positive results. The results of spinal endoscopic adhesiolysis are also positive.

Level of Evidence

The evidence for percutaneous adhesiolysis is strong in post-lumbar laminectomy syndrome. The positive results were observed for percutaneous adhesiolysis and spinal endoscopic adhesiolysis based on randomized controlled trials.

Utilizing the criteria applied in the ACOEM guidelines (33), the evidence is strong (A) for catheter based percutaneous adhesiolysis whereas, it is moderate (B) for endoscopic adhesiolysis.

Based on the quality of evidence developed by AHRQ USPSTF criteria (Table 3) (21) the evidence for both percutaneous and endoscopic adhesiolysis in managing post-lumbar laminectomy syndrome is Level I with evidence obtained from at least one properly randomized controlled trial.

Recommendations

Based on Guyatt et al's (19) grading strength of recommendations and quality of evidence in clinical guidelines, the recommendation is strong with 1A for percutaneous adhesiolysis in post-lumbar laminectomy syndrome, with benefits clearly outweighing the risks and burdens, with high quality supporting evidence derived from randomized controlled trials, with strong recommendations, which can apply to most patients in most circumstances without reservation. However, grading recommendation for endoscopic adhesiolysis is1B/strong recommendation with benefits clearly outweighing the risks and burdens, with moderate quality evidence.

Table 36. *Methodological assessment of randomized clinical trials evaluating effectiveness of adhesiolysis.*

Criterion		Weighted Score	Manchikanti et al (352)	Heavner et al (356)	Veihelmann et al (355)	Manchikanti et al (354)
Study population						
A	Homogeneity	2	2	2	2	2
B	Comparability of relevant baseline characteristics	5	5	5	5	5
C	Randomization procedure adequate	4	4	4	2	4
D	Drop-outs described for each study group separately	3	3	3	3	3
E	≤ 20% loss for follow-up	2	—	—	—	—
	≤ 10% loss for follow-up	2	—	—	—	—
F	> 50 subject in the smallest group	8	—	—	—	—
	> 100 subjects in the smallest group	9	—	—	—	—
Interventions						
G	Interventions included in protocol and described	10	10	10	10	10
H	Pragmatic study	5	5	5	5	5
I	Co-interventions avoided	5	—	—	—	—
J	Placebo-controlled	5	—	—	—	—
Effect						
K	Patients blinded	5	5	5	—	5
L	Outcome measures relevant	10	10	10	10	10
M	Blinded outcome assessments	10	10	10	3	10
N	Follow-up period adequate	5	5	5	5	5
Data-presentation and analysis						
O	Intention-to-treat analysis	5	5	—	—	5
P	Frequencies of most important outcomes presented for each treatment group	5	5	5	5	5
	TOTAL SCORE	**100**	**69**	**64**	**50**	**69**

Methodological criteria and scoring adapted from Koes BW et al. Efficacy of epidural steroid injections for low-back pain and sciatica: A systematic review of randomized clinical trials. *Pain* 1995; 63:279-288 (51).

Table 37 *Results of randomized trials of percutaneous adhesiolysis.*

Study	Participants	Intervention(s)	Outcome(s)	Result(s)	Conclusion(s) Short-term relief ≤ 6 mos Long-term relief > 6 mos
Veihelmann et al 2006 (355)	99 patients with chronic low back pain and sciatica (13 with prior back surgery). Nerve root compromise confirmed by MRI and CT. 52 patients treated with physiotherapy (control) • 5 prior surgery 47 underwent epidural neuroplasty (percutaneous adhesiolysis) •8 prior surgery PT patients could cross over after 3 months (12 patients crossed over).	Group I underwent physical therapy (no description of specific exercises) Group II underwent percutaneous adhesiolysis - Catheter placed through sacral hiatus to level of pathology after epidurogram to confirm position. - 9cc ropivacaine and 40mg triamcinolone catheter secured • 30 minutes later, 10cc of 10% saline instilled • Unclear whether this was a 1 day or 3 day protocol.	Timing: 3 months, 6 months, 12 months Outcome measures: VAS back, VAS leg, Oswestry disability score, Gerbershagen score, analgesic score.	Intention to treat analysis was performed. Among the adhesiolysis patients, there was a significant decrease in VAS and Oswestry scores at 1, 3, 6, and 12 months. 28 adhesiolysis patients were able to decrease I` Gerbershagen grade compared to 2 PT patients.	Positive short-term and long-term relief.
Manchikanti et al 2004 (352)	75 patients were evaluated 25 patients in Group I served as controls and were treated with catheterization but no adhesiolysis. 25 patients in Group II were treated with catheterization, adhesiolysis, followed by injection of local anesthetic, normal saline, and steroid. 25 patients in Group III. treatment consisted of adhesiolysis followed by injection of local anesthetic, hypertonic saline, and steroid.	Experimental groups: Adhesiolysis, hypertonic saline neurolysis, steroid and local anesthetic and adhesiolysis, normal saline, steroid. Control group: Catheterization and no adhesiolysis.	Timing: 3 months, 6 months, and 12 months. Outcome measures: VAS pain scale, Oswestry Disability Index 2.0, work status, opioid intake, range of motion measurements, and psychological evaluation by P-3.	72% of patients in Group III (adhesiolysis and hypertonic neurolysis), 60% of patients in Group II (adhesiolysis only), compared to 0% in Group I (control) showed significant improvement at 12-month follow-up.	Positive short-term and long-term relief.
Heavner et al 1994 (356)	59 patients with chronic intractable low back pain. All the patients failed conservative management, along with fluoroscopically directed epidural steroid injections.	Group I: hypertonic saline plus hyaluronidase Group II: hypertonic saline Group III: isotonic saline (0.9% NaCl) Group IV: isotonic saline plus hyaluronidase	Timing: 4 weeks, 3 months, 6 months, and 12 months. Outcome measures: Pain relief.	Initially 83% of the patients showed significant improvement compared to 49% of the patients at 3 months, 43% of the patients at 6 months, and 49% of the patients at 12 months.	Positive short-term and long-term relief.
Manchikanti et al 2005 (354)	A total of 83 patients were evaluated, with 33 patients in Group I and 50 patients in Group II. Group I served as the control with endoscopy into the sacral canal without adhesiolysis, followed by injection of local anesthetic and steroid. Group II consisted of spinal endoscopic adhesiolysis, followed by injection of local anesthetic and steroid. 73% of the patients in Group I and 84% of the patients in Group II were of post lumbar laminectomy syndrome and had MRI evidence of epidural fibrosis.	In Group I, guide wire and a 0.8 mm fiberoptic spinal endoscopic video guided system was introduced and advanced until the tip was positioned S3. Injections included 10 mL of 1% lidocaine and 6 mg to 12 mg of Celestone or 40 mg to 80 mg of methylprednisolone. In Group II, spinal endoscope was advanced to the level of suspected pathology. Adhesiolysis was carried out. Injections included 10 mL of lidocaine 1%, preservative free, mixed with 6 mg to 12 mg of betamethasone acetate or 40 mg to 80 mg of methylprednisolone.	Timing: 1 month, 3 months, 6 months, and 12 months Outcome measures: Pain relief by visual analog scale Significant pain relief 50% or greater. Oswestry Disability Index 2.0 Work status Opioid intake Range of motion measurement Psychological evaluation Return to work	Intention to treat analysis was performed. Among the 50 patients in the treatment group with spinal endoscopic adhesiolysis 80% at 3 months, 56% at 6 months, and 48% at 12 months showed significant improvement without adverse events. In control group improvement was noted only at one month. Group II patients showed improvement in Oswestry Disability Scores, psychological status, reduced opioid intake, and increased employment.	Positive short-term and long-term relief.

Adapted and modified from Trescot AM et al. Systematic review of effectiveness and complications of adhesiolysis in the management of chronic spinal pain: An update. *Pain Physician* 2007; 10: 129-146 (58).

Table 38. *Results of randomized trials of effectiveness of percutaneous and endoscopic lysis of lumbar epidural adhesions.*

Study	Study Characteristics	Methodological Quality Scoring		Participants	Pain Relief				Results	
					≤ 3 mos	3 mos	6 mos.	12 mos.	Short-term ≤6 mos	Long-term >6 mos
		ACOEM Score x 9.1	Reassessment Score							
Manchikanti et al 2004 (352)*	RA, DB	72.8	69	G1 = 25 G2 = 25 G3 = 25	33% 64% 72%	0% 64% 72%	0% 60% 72%	0% 60% 72%	P	P
Heavner et al 1999 (356)*	RA, DB	22.75	64	59	83%	49%	43%	49%	P	P
Veihelmann et al 2006 (355)*	RA	45.5	50	99	SI	SI	SI	SI	P	P
Manchikanti et al 2005 (354)	RA, DB	NUA	69	83	NA	80%	56%	48%	P	P

* Indicates use in ACOEM guidelines.
RA = randomized; DB = double blind; SI = significant improvement; P = positive; N = negative

Adapted and modified from Boswell MV et al. Interventional techniques: Evidence-based practice guidelines in the management of chronic spinal pain. *Pain Physician* 2007; 10:7-111 (1).

Intradiscal Therapies

There was a lack of recommendation for intradiscal electrothermal therapy (IDET) for treatment of acute, subacute, chronic low back pain, or any other back-related disorder, with strength of evidence as insufficient (33).

The rationale for the ACOEM guidelines recommendation (33) included 2 randomized controlled trials which provided conflicting results (362,363). Pauza et al (362) studied 64 patients and compared IDET with a sham treatment for patients with chronic low back pain and disc degeneration identified by discography. Pain ratings and Oswestry scores both decreased for IDET and sham groups even though the decreases in pain ratings and Oswestry scores were higher in the treatment groups. The authors of the guidelines (33) concluded that nonspecific factors associated with the procedure account for a proportion of the apparent efficacy of IDET, but its efficacy cannot be attributed wholly to a placebo effect. The second study by Freeman et al (363) evaluating IDET and sham treatment provided negative results.

Systematic Reviews and Conflicting Evidence

Boswell et al (1) in evidence-based guidelines preparation reviewed the evidence for IDET with the inclusion of 3 systematic reviews (71-73), a technology assessment update (74), a critical appraisal of the evidence (75), other reviews, randomized trials (362,363), and several prospective evaluations.

Appleby et al (72) in a systematic review from all the available studies concluded that there was compelling evidence for the relative efficacy and safety of IDET. Andersson et al (71), in another systematic review of spinal fusion and IDET in the treatment of intractable discogenic low back pain, concluded that the majority of patients reported improvement in symptoms following both spinal fusion and an IDET procedure, even though the IDET procedure appeared to offer sufficiently similar symptom amelioration to spinal fusion without attendant complications and less cost. In a third systematic review by Gibson and Waddell (73), it was concluded that IDET was ineffective, except possibly in highly selected patients.

In another review, Freeman (75) found that the evidence for the efficacy of IDET remains weak and has not passed the standard of scientific proof. Airaksinen et al (91) concluded that there is conflicting evidence that IDET, in patients with discogenic low back pain, is not more effective than sham treatment. The technology assessment update (69) concluded that initial results from the studies are promising even though the

Table 39. Methodological assessment of randomized clinical trials evaluating the effectiveness of published reports of intradiscal electrothermal therapy.

Criterion		WEIGHTED SCORE	Pauza et al (362)	Freeman et al (363)
Study population				
A	Homogeneity	2	2	2
B	Comparability of relevant baseline characteristics	5	5	5
C	Randomization procedure adequate	4	4	4
D	Drop-outs described for each study group separately	3	3	3
E	≤ 20% loss for follow-up	2	2	2
	≤ 10% loss for follow-up	2	—	2
F	> 50 subject in the smallest group	8	—	—
	> 100 subjects in the smallest group	9	—	—
Interventions				
G	Interventions included in protocol and described	10	10	10
H	Pragmatic study	5	5	—
I	Co-interventions avoided	5	—	—
J	Placebo-controlled	5	—	5
Effect				
K	Patients blinded	5	5	5
L	Outcome measures relevant	10	10	10
M	Blinded outcome assessments	10	10	10
N	Follow-up period adequate	5	2	2
Data-presentation and analysis				
O	Intention-to-treat analysis	5	—	—
P	Frequencies of most important outcomes presented for each treatment group	5	5	5
	TOTAL SCORE	100	63	65

Methodological criteria and scoring adapted from Koes BW et al. Efficacy of epidural steroid injections for low-back pain and sciatica: A systematic review of randomized clinical trials. *Pain* 1995; 63:279-288 (51).

majority of the data comes from small case series and studies, and also concluded that IDET is a controversial and is considered investigational until more randomized controlled trials with long-term follow-up can be conducted that may demonstrate the effectiveness of IDET.

The authors of the ACOEM guidelines excluded all systematic reviews (71-74).

Reassessment

Reassessment of the evidence was carried out even though the studies were the same as included in the ACOEM guidelines synthesis.

Methodological Quality Criteria

Methodologic quality criteria is illustrated in Table 39. Based on Cochrane review criteria both studies scored above 50 with Pauza et al study (362) scoring 63 and Freeman et al study (363) scoring 65, however, neither study evaluated the results beyond 6 months.

Study Characteristics

Table 40 describes the study characteristics of both studies. Both studies surprisingly used a randomization allocation of 2:1 ratio, and were sponsored by the same company. In Pauza et al's study (362), the control group used a different methodology and the catheter

Table 40. Characteristics of published reports of IDET.

Study/ Methods	Participants	Intervention(s)	Outcome(s)	Result(s)	Conclusion(s) Short-term relief ≤ 6 mos Long-term relief > 6 mos
Pauza et al 2004 (362)	Patients were recruited by referral and the media. No inducements were provided to any patient in order to have them participate. Of 1,360 individuals who were prepared to submit to randomization, 260 were found potentially eligible after clinical examination and 64 became eligible after discography. All had discogenic low back pain lasting longer than 6 months, with no comorbidity. Thirty-seven were allocated to IDET and 27 to sham treatment. Both groups were satisfactorily matched for demographic and clinical features.	IDET was performed using a standard protocol, in which the posterior annulus of the painful disc was heated to 90 C. Sham therapy consisted of introducing a needle onto the disc and exposing the patient to the same visual and auditory environment as for a real procedure. Thirty-two (85%) of the patients randomized to the IDET group and 24 (89%) of those assigned to the sham group complied fully with the protocol of the study, and complete follow-up data are available for all of these patients.	The principal outcome measures were pain and disability, assessed using a visual analog scale for pain, the Short Form (SF)-36, and the Oswestry disability scale.	Patients in both groups exhibited improvements, but mean improvements in pain, disability, and depression were significantly greater in the group treated with IDET. More patients deteriorated when subjected to sham treatment, whereas a greater proportion showed improvements in pain when treated with IDET. The number needed to treat, to achieve 75% relief of pain, was five. Whereas approximately 40% of the patients achieved greater than 50% relief of their pain, approximately 50% of the patients experienced no appreciable benefit.	Nonspecific factors associated with the procedure account for a proportion of the apparent efficacy of IDET, but its efficacy cannot be attributed wholly to a placebo effect. The results of this trial cannot be generalized to patients who do not fit the strict inclusion criteria of this study, but IDET appears to provide worthwhile relief in a small proportion of strictly defined patients undergoing this treatment for intractable low back pain.
Freeman et al 2005 (363)	Patients with CDLBP who failed to improve following conservative therapy were considered for this study. Inclusion criteria included the presence of one- or two-level symptomatic disc degeneration with posterior or posterolateral anular tears as determined by provocative computed tomography (CT) discography. Patients were excluded if there was greater than 50% loss of disc height or previous spinal surgery. Fifty-seven patients were randomized with a 2:1 ratio: 38 to IDET and 19 to sham procedure (placebo).	IDET was performed using a standard protocol, in which the posterior annulus of the painful disc was heated to 90° in the experimental group. In Sham therapy group the needle was introduced onto the disc. In the sham group the catheter was introduced however, no heat was applied. An independent technician connected the catheter to the generator and then either delivered electrothermal therapy (active group) or did not (sham group). All patients followed a standard post-procedural rehabilitation program.	Low Back Outcome Score (LBOS), Oswestry Disability Index (ODI), Short Form 36 questionnaire (SF-36), Zung Depression Index (ZDI), and Modified Somatic Perceptions Questionnaire (MSPQ) were measured at baseline and 6 months. Successful outcome was defined as no neurologic deficit, improvement in LBOS of greater then 7 points, and improvement in SF-36 subsets (physical function and bodily pain) of greater than 1 standard deviation.	Baseline demographic data, initial LBOS, ODI, SF-36, ZDI, and MSPQ were similar for both groups. No neurologic deficits occurred. No subject in either arm showed improvement of greater than 7 points in LBOS or greater than 1 standard deviation in the specified domains of the SF-36. Mean ODI was 41.42 at baseline and 39.77 at 6 months for the IDET group, compared with 40.74 at baseline and 41.58 at 6 months for the placebo group. There was no significant change in ZDI or MSPQ scores for either group.	The IDET procedure appeared safe with no permanent complications. No subject in either arm met criteria for successful outcome. Further detailed analyses showed no significant change in outcome measures in either group at 6 months. This study demonstrates no significant benefit from IDET over placebo.

was not inserted into the disc. The sham treatment commenced with the introducer needle firmly positioned against the outermost aspect of the annulus fibrosus instead of introducing the electrode, and the patient was exposed to a fluoroscopic monitor demonstrating the passage of an electrode. After a time period elapsed equal to that necessary for electrode placement, generator noises were produced for 16.5 minutes to mimic an active treatment. In contrast, Freeman et al (363) utilized the same randomization scheme of 2:1, but introduced the catheter in the sham group as well as the treatment experimental group. In the sham (placebo) group the generator was not connected. However, the results were quite dissimilar

Table 41. *Results of published randomized trials of IDET.*

Study	Study Characteristics	Methodological Quality Scoring		Participants	Pain Relief		Results	
		ACOEM Score x 9.1	Reassessment Score		≤ 6 mos	6 mos	Short-term relief ≤6 mos	Long-term relief >6 mos
Pauza et al 2004 (362)*	RA, DB, PC	77.35	63	C = 27 T = 37	NSD	38% vs 33%	N	NA
Freeman et al 2005 (363) *	RA, DB, PC	77.35	65	C = 19 T = 38	NSD	NSD	N	NA

* Indicates use in ACOEM guidelines.

RA = randomized; DB = double blind; PC = placebo controlled; C= control; T = treatment; NSD = no significant difference; N = negative; *NA = not available*

Adapted and modified from Boswell MV et al. Interventional techniques: Evidence-based practice guidelines in the management of chronic spinal pain. *Pain Physician* 2007; 10:7-111 (1).

with one author (362) promoting IDET as a successful treatment, and other author (363) promoting a lack of effectiveness.

Results

Results are illustrated in Table 41 for both randomized controlled trials. Based on these results, Pauza et al (362) showed improvement in both groups, but mean improvements in pain, disability, and depression were significantly greater in the group treated with IDET. Further, more patients deteriorated when subjected to sham treatment, whereas a greater proportion showed improvements in pain when treated with IDET. They showed that the number needed to treat, to achieve 75% relief of pain, was 5; however, approximately 40% of the patients achieved greater than 50% relief of their pain, approximately 50% of the patients experienced no appreciable benefit. Pauza et al (362) showed that 38% of the patients treated with IDET showed improvement at 6 months, whereas only 33% of the patients showed improvement undergoing sham treatment. However, in Pauza et al's study, patients experiencing relief of 2 points on VAS was 56% in the IDET group and 38% in the sham group. Freeman et al (363) showed no significant differences in short-term or long-term relief.

Level of Evidence

Based on the strict criteria of inclusion of only randomized trials, the evidence is insufficient (1,33). However, utilizing the criteria developed by AHRQ USPSTF criteria (Table 3) (21) and 2 (71,72) of the 4 positive systematic reviews (71-74), the evidence for IDET appears to be II-2 in managing chronic discogenic low back pain considering the cost effectiveness of this modality compared to other treatments available for the same condition.

Recommendations

No recommendation is available based on evidence derived from randomized trials, however, based on the observational evidence and evidence derived from systematic reviews utilizing Guyatt's criteria (19), the recommendation is 2A/weak recommendation, with high-quality evidence, with benefits closely balancing the risks and burdens, with overwhelming evidence derived from observational studies with best action depending on circumstances or patients' or societal values.

Percutaneous Disc Decompression

The ACOEM guidelines (33) described percutaneous disc decompression in conjunction with surgical decompression under the heading of lumbosacral nerve root decompression in which percutaneous adhesiolysis was also included.

The guidelines (33) describe direct methods of nerve root decompression such as surgical decompression along with indirect methods of nerve decompression which potentially include chemonucleolysis with chymopapain, low-dose radiotherapy for inhibition of fibrosis, IDET, and percutaneous discectomy either by mechanical, electrical, or laser methods. The guidelines (33) recommend lumbar discectomy as an

effective operation to speed recovery in patients with radiculopathy due to ongoing nerve root compression who continue to have significant pain and functional limitation after 4-6 weeks of time and appropriate conservative therapy with strength of evidence of B with moderate recommendation. However, the ACOEM guidelines (33) have not recommended percutaneous discectomy (nucleoplasty), laser discectomy, and disc coblation therapy as treatment for any back or radicular pain syndrome with evidence strength of B.

The ACOEM guidelines considered 16 moderate-quality randomized controlled trials or quasi- randomized controlled trials incorporated in this analysis with review of 5 systematic reviews and 2 low-quality studies in the appendix.

The ACOEM guidelines (33) included 3 randomized trials evaluating the effectiveness of percutaneous discectomy (364-366). Chatterjee et al (364) compared automated percutaneous lumbar discectomy (APLD) and microdiscectomy among 71 patients with a contained lumbar disc herniation. The patients primarily had radicular pain and had failed a minimum of 6 weeks of conservative treatment. Those with primarily back pain were excluded. The success rates combining excellent and good were 29% for APLD vs. 80% for microdiscectomy. They concluded that APLD was ineffective as a method of treatment for small, contained lumbar disc herniations. The second study for percutaneous discectomy was by Revel et al (365) comparing chemonucleolysis with APLD for treatment of 141 patients with sciatica. The results showed that at 6-month follow-up, 61.1% in the chemonucleolysis group vs 43.5% in the automated percutaneous discectomy were self-rated very good or good. The authors of this study concluded that the results of both treatments are generally disappointing. A third study by Haines et al (366) compared conventional open discectomy with automated percutaneous discectomy for 36 patients with herniated lumbar discs. Even though baseline differences favored the conventional open discectomy over automated percutaneous discectomy, the data suggest that neither group reported favorable surgical results.

Waddell et al (367) in a systematic review based on Cochrane Collaboration and meta-analysis of surgical interventions in the lumbar spine (73), identified 3 trials comparing automated percutaneous discectomy with other surgical techniques and concluded there was limited and contradictory evidence (Strength of Evidence C) that APLD gives poorer clinical results than alternative surgical techniques with which it has been compared. In a technology assessment report (74) they evaluated randomized trials (364-366,368,369) of which Haines et al had 2 publications from one study (366,368). Evidence from 4 of the 4 randomized published studies was shown to be negative, while all observational studies were positive.

Percutaneous laser discectomy (PLD) also is an alternative to the standard open discectomy treatment. This modality has not been considered in the ACOEM guidelines (33). Based on the systematic review by Waddell et al (367) there is no acceptable evidence (strength of evidence D) for laser discectomy. There were no relevant randomized studies evaluating the effectiveness of laser disc decompression.

Reassessment

Methodologic Quality Assessment

Methodologic quality criteria assessment of randomized studies showed poor evidence criteria, not meeting inclusion criteria, thus it is not systematically reported here.

Level of Evidence

Results of this evaluation showed limited evidence based on the ACOEM criteria (33). However, based on the quality of evidence developed by AHRQ USPSTF criteria (Table 3) (21) evidence is Level II-2.

Recommendations

Based on the Guyatt et al's (19) criteria, the recommendation falls into category of 2B/weak recommendation with moderate quality evidence, obtained from randomized controlled trials with important limitations and strong evidence from observational studies, with benefits closely balanced with risks and burden, with weak recommendation, with best action differing based on circumstances or patients' or societal values.

Spinal Cord Stimulation

The ACOEM guidelines have slightly separate descriptions of spinal cord stimulation in the low back pain chapter (33) and the chronic pain chapter (34). In the low back pain chapter the descriptions are limited to low back pain only with or without lower extremity pain, whereas, in the chronic pain chapter other indi-

cations are described, including the use of spinal cord stimulators for the treatment of numerous painful conditions such as chronic low back pain (370-373), radicular syndromes, angina pectoris, peripheral arterial disease, CRPS, and peripheral neuropathy (33,374).

Poor Selection Criteria and Evidence Synthesis by the ACOEM Guidelines

The ACOEM guidelines (33,34) provide conflicting and weak recommendations of spinal cord stimulation for treatment of acute, subacute, or chronic low back pain. They also did not recommend them for treatment of radicular pain syndromes or failed back surgery syndrome due to insufficient evidence (33). ACOEM guidelines (34) concluded that, for highly selected CRPS types I or II patients who unequivocally understand that this intervention has no demonstrated long-term benefits, and rather is used for short to intermediate durations during which time a functional restoration program is unequivocally committed and adhered to, spinal cord stimulation is recommended. They utilized one moderate-quality randomized controlled trial in the analysis and commented that none of the studies are of sufficient quality for the development of evidence-based guidance.

In the appendix, they quoted 3 systematic reviews, one set of guidelines, and 4 low quality studies (33,34). The studies reviewed for low back pain were by Kumar et al (375) and North et al (380). Kumar et al (375) compared spinal cord stimulation with a conventional medical management arm for treatment of radicular pain syndrome symptoms from any of the L4-S1 nerve roots. The medical management in both groups was "actively managed." Of those who were randomized to medical management, by 12 months, only 25% (16/48) remained in that arm, whereas, 28 had crossed over to spinal cord stimulation. Five of those in the spinal cord stimulation group crossed over to chronic pain management group at 6 months. By 12 months, the protocol analysis showed 34% of the spinal cord stimulation group and 7% of the medical management group achieving at least 50% pain relief. The authors (375) concluded that compared with the medical management group, the spinal cord group experienced improved leg and back pain relief, quality of life, and functional capacity, as well as greater treatment satisfaction. The compliance rate in the conventional treatment was low (33%), which raised questions by the authors of guidelines (33) about the results. The medical management was criticized as being unstructured, with numerous potential confounders and utilization co-interventions (33). The guideline authors also criticized the sharp reduction in the number who achieved the 50% pain relief target at 12 months (reduction from 48% to 34%), suggesting that the benefits, even if real, are not long term.

The second study they included in failed laminectomy syndrome is of North et al (380) described as a low-quality study in which surgical treatment was individualized among the randomized group included discectomy, laminectomy, foraminotomy, fusion, and instrumentation. Long-term success rates at 2.9 ± 1.1 years were spinal cord stimulation 47% vs reoperation 12%, $P \leq 0.01$. ACOEM guidelines authors (33) criticized that this study tests spinal cord stimulation versus reoperation, but does not document how it would compare with a quality functional restoration program. They also added, that reoperation may be critiqued for analogous to "more of the same" that had previously failed, thus producing a potential bias in favor of the new treatment.

For chronic pain other than low back pain, specifically for highly selected CRPS types I or II patients, the authors of the guidelines (34) utilized one moderate quality randomized controlled trial that spinal cord stimulation results in reduced pain for CRPS that is sustained over periods up to 3 years (376-378). The guidelines described that from years 3 to 5, there was no benefit from spinal cord stimulation. The authors (34) commented that there is not a quality study that appears to compare spinal cord stimulation with a multidisciplinary treatment program that emphasizes functional restoration.

Conflicting Evidence

In the United States, the primary indications for spinal cord stimulation are failed back surgery syndrome and CRPS, Type I and Type II (78-83). Multiple systematic reviews (78-83), guidelines (1,85-87), and 3 randomized trials (370,375-381) have been published. The studies by Kemler et al (376-379,381), Kumar et al (375), and North et al (380) were utilized in the ACOEM guidelines. However, one study by North et al (370) was not included. North et al (370,380) evaluated failed back surgery syndrome patients who underwent repeat spinal surgery or spinal cord stimulation and found favorable results with spinal cord stimulation superior to reoperation through 3-year follow-up.

Taylor et al (78,81-83) evaluated various aspects of spinal cord stimulation in a series of systematic reviews and meta-analyses. In a systematic review and analysis of prognostic factors published in 2005, Taylor et al (78) concluded that, "despite an increase in the number of studies, the level of evidence for the efficacy of spinal cord stimulation in chronic back and leg pain or failed back surgery syndrome remained moderate." Prognostic factors found to be predictive of the level of pain relief following spinal cord stimulation were study quality, follow-up duration, study setting, and patient indication. Taylor (81) published in 2006 results of a systematic review and meta-analysis of spinal cord stimulation in complex regional pain syndrome (CRPS) and refractory neuropathic back and leg pain / failed back surgery syndrome. It was concluded that use of spinal cord stimulation in patients with refractory neuropathic back and leg pain/failed back surgery syndrome (Grade B evidence) and CRPS type I (Grade A evidence) / Type II (Grade B evidence), not only reduces pain, improves quality of life, reduces analgesic consumption, and allows some patients to return to work, with minimally significant adverse events, but may also result in significant cost savings over time. Taylor et al (83) also evaluated the cost effectiveness of spinal cord stimulation in the treatment of pain. They concluded that across a range of medical indications, the initial health care acquisition cost of spinal cord stimulation implantation are consistently offset by a reduction in post-implant health care resource demand and costs.

Furthermore, others reported evidence to support the long-term cost effectiveness of spinal cord stimulation compared to other standard modalities used for treatment of failed back surgery syndrome with a cost of $29,123 in the spinal cord stimulation group and $38,029 in the control group (382). There is also an estimated savings of $60,000 over lifetime use in CRPS.

Turner et al (79) conducted a systematic review of the literature on the effectiveness of spinal cord stimulation in relieving pain and improving function for patients with failed back surgery syndrome and CRPS. They suggested methodologically stronger studies to provide more definitive data regarding the effectiveness of spinal cord stimulation in relieving pain and improving functioning, short- and long-term, among patients with chronic pain syndrome. Cameron's 20-year literature review (383) included studies totalling 3,679 patients and showed that spinal cord stimulation has a "positive, symptomatic, long-term effect in cases of refractory angina pain . . ." as well as with peripheral vascular disease, peripheral neuropathic pain, and chronic low back pain. It was also concluded that spinal cord stimulation is safe and effective for treatment of chronic neuropathic pain. Boswell et al (1) concluded that evidence for spinal cord stimulation in failed back surgery syndrome and CRPS is moderate for long-term relief of 1-year or longer.

The ACOEM guidelines (33,34) do not recommend spinal cord stimulation for any type of pain due to insufficient evidence except in rare circumstances for short-term or intermediate-term relief.

Some of the criticisms by the ACOEM guidelines (33,34) include lack of comparison with multidisciplinary programs — functional restoration programs — a modality that is not been supported by evidence-based medicine. Work hardening and functional restoration have not usually been approved by insurers, and thus, these programs have become extinct except in very select areas.

Reassessment

Due to non-recommendation of spinal cord stimulation for any type of pain, except in rare circumstances for short-term or intermediate-term relief, a reassessment of evidence was undertaken.

Methodologic Quality Assessment

Three studies were identified meeting inclusion criteria, which were randomized (375,376,379,380). Table 42 illustrates methodologic assessment scores. All 3 studies scored above 50, however, ranging from 54 to 56. Methodologic quality assessment indicates the difficulties associated with surgical interventions and randomized trials with loss for follow-up, number of participants in each group, inability to avoid co-interventions, inability to have a true placebo control and double blinding of patients. Among these studies, 2 studies evaluated failed back surgery syndrome (375,380), whereas the third study evaluated the effectiveness of spinal cord stimulation for reflex sympathetic dystrophy (376,379,381). Kumar et al (375) compared 100 failed back surgery syndrome patients with predominant leg pain of neuropathic origin with spinal cord stimulation or conventional medical management and demonstrated positive short- and long-term results. Kemler et al (376), evaluating the chronic reflex sympathetic dystrophy, published their results

Table 42. *Methodological assessment of randomized clinical trials evaluating spinal cord stimulation.*

Criterion		WEIGHTED SCORE	Kumar et al (375)	Kemler et al (376,379,381)	North et al (380)
Study population					
A	Homogeneity	2	2	2	2
B	Comparability of relevant baseline characteristics	5	4	5	2
C	Randomization procedure adequate	4	4	4	4
D	Drop-outs described for each study group separately	3	3	3	3
E	≤ 20% loss for follow-up	2	2	—	—
	≤ 10% loss for follow-up	2	—	—	—
F	> 50 subject in the smallest group	8	—	—	—
	> 100 subjects in the smallest group	9	—	—	—
Interventions					
G	Interventions included in protocol and described	10	10	10	10
H	Pragmatic study	5	5	5	5
I	Co-interventions avoided	5	—	—	—
J	Placebo-controlled	5	—	—	—
Effect					
K	Patients blinded	5	—	—	—
L	Outcome measures relevant	10	10	10	10
M	Blinded outcome assessments	10	—	—	10
N	Follow-up period adequate	5	5	5	5
Data-presentation and analysis					
O	Intention-to-treat analysis	5	5	5	—
P	Frequencies of most important outcomes presented for each treatment group	5	5	5	5
TOTAL SCORE		**100**	**55**	**54**	**56**

Methodological criteria and scoring adapted from Koes BW et al. Efficacy of epidural steroid injections for low-back pain and sciatica: A systematic review of randomized clinical trials. *Pain* 1995; 63:279-288 (51).

in a series of 3 articles. The results were positive for short-term relief, whereas were negative for long-term relief. Finally, North et al (380) evaluated 2 surgical procedures, namely spinal cord stimulation and compared with reoperation showing positive short- and long-term results with spinal cord stimulation.

Study Characteristics

Salient study features are described in Table 43.

Results

Results of published reports of spinal cord stimulation are illustrated in Table 44. Long-term results were available in all 3 studies. Of these, evidence for failed back surgery syndrome with neuropathic pain, the results are positive for short and long-term. However, the evidence for reflex sympathetic dystrophy is positive for short-term relief, whereas, it is negative for long-term relief.

Level of Evidence

Based on ACOEM guideline synthesis criteria (33), the evidence for spinal cord stimulation in managing failed back surgery syndrome is strong (A) for short and long-term relief, whereas, it is moderate (B) for short-term relief and insufficient (I) for long-term relief in reflex sympathetic dystrophy in managing CRPS. Based on AHRQ USPSTF criteria (Table 3) (21), the evi-

Table 43. *Description of randomized trials of spinal cord stimulation.*

Study/ Methods	Participants	Intervention(s)	Outcome(s)	Result(s)	Conclusion(s) Short-term relief ≤ 12 mos Long-term relief > 12 mos
Kumar et al 2007 (375) Randomized controlled trial	100 failed back surgery syndrome patients with predominant leg pain of neuropathic radicular origin were studied with either spinal cord stimulation plus conventional medical management (SCS group) or conventional medical management alone (CMM group).	48 patients were assigned to conventional medical management group and 52 patients were assigned to spinal cord stimulation group. Spinal cord stimulation group also received conventional medical management in addition to spinal cord stimulator.	The primary outcome was a proportion of patients achieving 50% or more pain relief in the legs. Secondary outcomes were improvement in back and leg pain, health-related quality of life, functional capacity, use of pain medication and non-drug pain treatment. The follow-up was at 6 months and 12 months.	At 6 months compared with the CMM group, SCS group patients experienced lower levels of back pain and leg pain, enhanced health-related quality of life, superior function, and greater treatment satisfaction. At 12 months the primary outcome was achieved in 58% of the 71 patients implanted with the simulator and 18% of the 17 patients receiving conventional medical therapy alone with 50% leg pain relief.	Significant improvement at 6 months and 12 months in patients receiving spinal cord stimulation and conventional medical therapy. Positive short-term and long-term relief.
Kemler et al 2000/2006/1999 (376,379,381) Randomized controlled trial	Randomized trial involved 36-patients who had reflex sympathetic dystrophy for at least 6 months with significant disability. 36 patients were assigned to receive treatment with spinal cord stimulation plus physical therapy and 18 were assigned to receive physical therapy alone.	The test stimulation of the spinal cord was successful in 24 patients.	Pain relief, SCL-90, health-related quality of life	Spinal cord stimulation group had a mean reduction of 2.4 cm in the intensity of pain at 6 months, as compared with an increase of 0.2 cm in the physical therapy group. At 5 years, the mean pain intensity in the stimulation group was reduced from baseline by 1.7 cm as compared to 1 cm in the control group (P=0.25). Similar results were obtained at follow-up at 3 years and at 4 years.	Positive for short-term relief. Negative for long-term relief.
North et al 2006 (380) Randomized controlled trial	Twenty-four patients were randomized to spinal cord stimulation trial and 26 were randomized to reoperation. Of these 17 underwent spinal cord stimulator implant. Further, 14 of the patients from reoperation randomization underwent spinal cord stimulation trial and received implant. Only one patient in spinal cord stimulator trial underwent reoperation.	The SCS patients received a permanent implant if they reported at least 50% estimated relief of pain by standard pain rating methods and demonstrated stable or improved analgesic medication intake, with improved physical activity commensurate with neurological status and age. Reoperation involved laminectomy and/or foraminotomy and/or discectomy in all patients with or without fusion, with or without instrumentation.	Outcomes were evaluated 6 months after the initial study procedure and annually thereafter, at least annually with an average of 3 years post-operatively. Success was based on self-reported pain relief and patient satisfaction. Cross-over to the alternative procedure was also an outcome measure. Other outcome measures included use of analgesics, activities of daily living, and work status – all self-reported.	Among 45 patients 90% available for follow-up, SCS was more successful than reoperation (9 of 19 patients versus 3 of 26 patients, P≤0.01). Patients initially randomized to SCS were significantly less likely to cross-over than were those randomized to reoperation (5 of 24 patients versus 14 of 26 patients, P=0.02). Patients randomized to reoperation required increased opiate analgesics significantly more often than those randomized to SCS. Other measures of activities of daily living and work status did not differ significantly.	SCS is more effective than reoperation as a treatment for persistent radicular pain after lumbosacral spine surgery, and in the great majority of patients, it obviates the need for reoperation. Positive short-term and long-term relief.

Table 44. Results of published reports of spinal cord stimulation.

Study	Study Characteristics	Methodological Quality Scoring		Patients	Pain Relief		Results	
		ACOEM Score x 9.1	Reassessment Score		≤ 12 mos	12 mos.	Short-term ≤12 mos	Long-term > 12 mos
Kumar et al 2007 (375)*	RA	59.15	55	SCS=52 CMM=48	48% vs 9%	58% vs 17%	P	P
Kemler et al 2000/2006 /1999 (376,379,381)*	RA	63.7	54	SCS=236 PT=18	SI in SCS	NA	P	N
North et al 2006 (380)*	RA	50.05	56	SCS=24 Reoperation=26	SCS 9/19 Reoperation 3/26	SCS 9/19 Reoperation 3/26	P	P

* Indicates use in ACOEM guidelines.

RA = randomized; DB = double blind; R = retrospective; C = control; T = treatment; NA = not available; SI = significant improvement; NSI = no significant improvement; P = positive; N = negative

Adapted and modified from Boswell MV et al. Interventional techniques: Evidence-based practice guidelines in the management of chronic spinal pain. *Pain Physician* 2007; 10:7-111 (1).

dence for spinal cord stimulation in managing failed back surgery syndrome is Level I for short- and long-term relief. However, the evidence for CRPS is Level II-1 for short-term relief and Level II-3 for long-term relief.

Based on Guyatt et al's criteria (19), the recommendation for spinal cord stimulation in managing CRPS, the recommendation is variable from 1C to 2A with 1C/strong recommendation, low-quality evidence, with benefit clearly outweighing the risks and burdens, methodologic quality of supporting evidence from observational studies, with a strong recommendation which may change when higher quality evidence becomes available. The 2A recommendation signifies weak recommendation, high-quality evidence overwhelmingly derived from observational studies, with benefits closely balanced with risks and burden with weak recommendation in which best action may differ depending on circumstances of patients' or societal values.

The recommendation for spinal cord stimulation in managing failed back surgery syndrome is 1A/ strong recommendation with moderate to high quality evidence, with benefits clearly outweighing the risks and burdens, based on randomized controlled trials, with strong recommendations which can apply to most patients in most circumstances without reservation.

Intrathecal Infusion Systems

The ACOEM guidelines evaluate implantable drug delivery systems under the category of "pain pumps" along with intrathecal baclofen (34), other drugs, and nerve blocks. They concluded that there is no evidence for intrathecal baclofen and consequently it is not recommended. The study utilized for the evaluation of intrathecal baclofen was that of van Hilten et al (384).

Available Evidence

Continuous infusion of intrathecal medication is used for the control of chronic, refractory, malignant or non-malignant pain. In an exhaustive review of the available literature, Bennett et al (385) concluded that clinical efficacy in a large-scale randomized controlled trial utilizing intrathecal delivery of most compounds has not been demonstrated, noting that variations between study designs make useful comparisons of existing studies difficult. Turner et al (84), in a systematic review of the effectiveness and complications of programmable intrathecal opioid delivery systems for chronic non-malignant pain, included 6 studies in their evidence synthesis and found improvement among patients who received a permanent intrathecal drug delivery system (386-391). Boswell et al (1) concluded that there is moderate evidence for long-term man-

agement of chronic pain with intrathecal infusion systems of 1-year or longer.

Among the randomized trials (384,392-394), Siddall et al (392) compared the effectiveness of intrathecal morphine or clonidine, alone or in combination, in the treatment of neuropathic pain after spinal cord injury and concluded that the combination of morphine and clonidine produced significantly more pain relief than placebo 4 hours after administration. van Hilten et al (384) evaluated the use of intrathecal baclofen for the treatment of dystonia in patients with CRPS, in a double-blind, randomized, controlled, crossover trial of bolus intrathecal injections of baclofen in various doses. They reached a conclusion that in some patients, the dystonia associated with reflex sympathetic dystrophy responded markedly to intrathecal baclofen. This study was included for consideration for baclofen in the ACOEM guidelines. Smith et al (393) compared intrathecal infusion systems with conventional aggressive medical management in patients with malignant pain and reported significant improvement in patients treated with intrathecal infusion systems. Staats et al (394), in a multicenter, double-blind trial, reported that a neuron-specific calcium channel blocker (ziconotide) delivered via an implanted intrathecal pump in patients with cancer and AIDS-related pain syndromes significantly decreased pain scores in 51% of the patients compared to 18% in the placebo group at the 7-day follow-up.

Cost effectiveness evaluations showed intrathecal morphine delivery resulting in lower cumulative 60-month costs of $16,579 per year, $1,382 per month versus medical management at $17,037 per year, $1,420 per month (395). Cost effectiveness also was evaluated in another study (396) with the expected total cost of intrathecal morphine over 60 months of $82,893, an average of $1,382 per month.

However, all the randomized trials evaluated only short-term relief. The long-term relief evaluations are derived from prospective and retrospective evaluations (386-391,397-408). Turner et al (80) in their systematic review of effectiveness and complications of programmable intrathecal opioid delivery systems for chronic non-malignant pain included 6 studies in the evidence synthesis and found improvement in pain on average among patients who received a permanent intrathecal drug delivery system (386-391).

Hassenbusch et al (397) reported favorable results in patients with long-standing non-malignant neuropathic pain in a study of 14 patients, with 61% reporting good or fair pain control with a mean follow-up duration of 2.4 years.

Angel et al (398) reported good to excellent analgesic response in 73% of 11 patients. Deer et al (391) reported the results of the National Outcome Registry for low back pain collected at 6- and 12-month follow-ups. The report concluded that in the implant group, numeric pain ratings dropped by more than 47% for back pain and more than 31% for leg pain at 12-month follow-up. They also reported 65% improvement in Oswestry Disability scores. Anderson and Burchiel (386) in 30 patients implanted with diverse diagnosis including 14 patients with failed back surgery syndrome showed positive outcomes. Kumar et al (387,389), Rainov et al (388), and Anderson et al (390) also showed positive outcomes.

Thimineur et al (402) evaluated the long-term outcome of intrathecal opioid therapy in chronic non-malignant pain prospectively and included 2 comparative groups to improve understanding of selection criteria and relative severity of intrathecal pump recipients. A total of 88 pump candidates agreed to participate and 69 of those completed the study. Thirty-eight patients comprised the pump-implants and 31 patients entered in the non-recipient group. The outcome data suggest that intrathecal treatment had a significant impact on pain, function, and mood among study patients and non-recipients deteriorated.

Zahavi et al (403) evaluated long-term effectiveness of intrathecal baclofen on impairment, disability, and quality of life in patients with severe spasticity of spinal origin. They showed significant improvement in clinical efficacy at 26 weeks. Deer et al (404) reported clinical experience with intrathecal bupivacaine in combination with opioid for the treatment of chronic pain related to failed back surgery syndrome and metastatic cancer pain of the spine. In this retrospective evaluation of 109 consecutive patients, the results showed that combination was significantly better.

Shaladi et al (400) reported the effectiveness of continuous intrathecal morphine infusion in patients with vertebral fractures due to osteoporosis. In 24 patients, refractory to conventional delivery of opioids, effectiveness of the treatment and quality of life improvement was illustrated. Koulousakis et al (401) reported their experience with a follow-up exceeding 3 years, with reduction of non-malignant pain in the range of good or excellent in 165 patients.

Assessment of Evidence

All the randomized trials were only of short duration and the long-term studies included prospective and retrospective. There were no randomized trials evaluating long-term relief. Thus, based on ACOEM guideline evidence synthesis (33), we are unable to perform evidence assessment. For ACOEM assessment, there is no provision for evaluation of prospective and retrospective studies, even though, AHRQ level of evidence criteria do include prospective and retrospective studies and case reports.

Level of Evidence

Based on prospective and retrospective studies, the evidence for implantable intrathecal infusion systems is moderate (Level II-2) for long-term management of chronic non-cancer pain.

Recommendations

Based on Guyatt et al's (19) criteria, the recommendation is 1C/strong with benefits clearly outweighing the risks and burdens, with exceptionally strong evidence derived from observational studies, with strong recommendation which can apply to most patients in most circumstances, but strong recommendation may change when higher quality evidence becomes available.

Discussion

The reassessment and reevaluation of the low back pain and chronic pain chapters of the ACOEM guidelines (33,34) indicates lack of sequential process for developing guidelines as described by Atkins et al (20), lack of inclusion of grading recommendations of Guyatt et al (19), and utilization of outdated quality of evidence criteria (33) adapted and modified from extinguished AHCPR (23). As shown in Table 5 strong evidence-base is the evidence from 2 or more high-quality studies which are defined as follows: For therapy and prevention, randomized controlled trials (RCTs) with narrow confidence intervals and minimal heterogeneity. For diagnosis and screening, cross sectional studies using independent gold standards. For prognosis, etiology, or harms, prospective cohort studies with minimal heterogeneity.

For moderate evidence base they described at least one high quality study or multiple moderate-quality studies relevant to the topic and the working population. While the high quality recommendation remains to be the same, the next recommendation for therapy and prevention, is a well-conducted review of cohort studies. Similarly, for prognosis, etiology, or harms, a well-conducted review of retrospective cohort studies or untreated control arms of RCTs. While this quality of evidence criteria utilized by ACOEM guidelines clearly describes for strong evidence for diagnosis and screening, cross sectional studies using independent gold standards. However, no such levels were provided for other moderate to insufficient evidence. Further they failed to utilize their own philosophy and demanded randomized controlled trials in the diagnosis.

Based on the reevaluation with utilization of only randomized trials for therapeutic interventions and observational diagnostic studies, vastly different results were found in this evaluation. Table 45 illustrates the variations in the diagnostic interventions, whereas Tables 46 and 47 illustrate variations in the strength of evidence and recommendations for therapeutic interventions.

The development process of the guidelines by ACOEM appears to be inappropriate (33,34). Deficiencies were identified in all areas. However, the major impact is based on utilization of outdated methodologic quality criteria, evidence assessment criteria, literature search, methodologic quality assessment criteria without weighted values, inappropriate application of the criteria, and lack of conflict management. Authors also have not utilized a sequential process for developing guidelines and application of grading and recommendations.

The differences in strength of rating for the diagnosis of discogenic pain by provocation discography, and facet joint pain by diagnostic facet joint nerve blocks is identified with strong evidence (A) by ACOEM criteria and Level I by AHRQ USPSTF criteria (21) (Table 3). The evidence for diagnosis of sacroiliac joint pain by diagnostic sacroiliac joint blocks is moderate (B) by ACOEM criteria and Level I by AHRQ USPSTF criteria (21) (Table 3). Similarly, for therapeutic techniques, therapeutic cervical and lumbar medial branch blocks and radiofrequency neurolysis, therapeutic thoracic medial branch blocks, cervical interlaminar epidural steroid injections, caudal epidural steroid injections, lumbar transforaminal epidural injections, percutaneous and endoscopic adhesiolysis, and spinal cord stimulation presented with moderate to strong evidence based on ACOEM (A or B), Level I to II based on AHRQ USPSTF criteria except for few subgroups. Further, the evidence rating for intrathecal infusion systems, IDET,

Table 45. *Evidence synthesis comparison of diagnostic blocks in interventional pain management.*

Procedure	ACOEM Conclusions		Present Evaluation			
	Strength of Evidence	Recommendation	Strength of Evidence		Recommendations Based on Guyatt et al's criteria (19)	
			ACOEM Criteria	AHRQ USPSTF Criteria	ACOEM Criteria	AHRQ USPSTF Criteria
Lumbar medial branch blocks	Insufficient Evidence (I)	No Recommendation	Strong	I	1A	1A
Cervical medial branch blocks	Insufficient Evidence (I)	Not Recommended	Strong	I	1A	1A
Thoracic medial branch blocks	N/A	N/A	Strong	I	1A	1A
Lumbar provocation discography	Evidence (B)	Moderately Not Recommended	Strong	I	1A	1A
Sacroiliac joint injections	Insufficient Evidence (I)	Not Recommended	Moderate	I	1B	1A

A: strong evidence-base
B: moderate evidence-base
C: limited evidence-base
I: insufficient evidence

1A/strong recommendation, high-quality evidence
1B/strong recommendation, moderate quality evidence
1C/strong recommendation, low-quality or very low-quality evidence

and automated percutaneous disc decompression is variable from limited to insufficient by ACOEM criteria and Level II by AHRQ USPSTF criteria (21) (Table 3).

Based on Guyatt et al's (19) described criteria, recommendations are also provided based on ACOEM evidence synthesis as well as AHRQ USPSTF criteria (2) (Table 3). Interventional techniques are variable from 1A to 1C with sacroiliac joint interventions, blind lumbar interlaminar epidural injections, percutaneous disc decompression, percutaneous automated disc decompression, and caudal epidural injections for post-lumbar laminectomy syndrome. Spinal cord stimulation for CRPS and intrathecal implantable systems received recommendations from 1C to 2C, varying from strong to very weak recommendation.

Interventional techniques and these techniques including issues related to the pathophysiology and underlying mechanism of action of steroid and local anesthetic injections are poorly understood. As such, the ACOEM authors used the issues adversely. Epidural corticosteroids have been postulated to provide a certain level of efficacy by the anti-inflammatory, immunosuppressive, anti-edema effects, and inhibition of neurotransmission within the C-fibers (409-412). In contrast, local anesthetics have been described to provide short-term symptomatic relief (413-415). However, local anesthetics also provide long-term relief with postulations explaining that the effectiveness of local anesthetics may be related to the direct effects of local anesthetic on various mechanisms in chronic pain (413-415). Thus, the focus may also be combined with pathophysiologic mechanisms of inflammation and nociception of the disc material to pathophysiologic mechanisms that form the basis for chronic pain which not only include nociceptive stimulation, but also excess nociception resulting in the sensitization of the pain pathways at several neuronal levels (414,415) and excess release of neurotransmitters causing complex central responses including hyperalgesia or windup (413). Consequently, all the responses of chronic pain mechanisms may result in an increase in nociceptive sensitization of the nervous system (416,417), and phenotype changes which are also considered as part of neuronal plasticity (416-419). Paradoxically, corticosteroids are not effective in neuropathic pain, whereas local anesthetics have been shown to be effective in the management of neuropathic pain, including the prevention of onset and the treatment of phantom-limb syndrome (415,419-423). Thus, it is postulated that local anesthetics provide relief by suppression of nociceptive discharge (424), the block of the axonal transport (425,426), the block of the sympathetic reflex arc (411,423), the block of sensitization (414,415), anti-inflammatory effect (426,427), and blockade of

Table 46. *Evidence synthesis comparison of therapeutic spinal interventional techniques.*

Procedure	ACOEM Conclusions		Present Evaluation (Long-term only)			
	Strength of Evidence	Recommendation	Strength of Evidence		Recommendations Based on Guyatt et al's criteria (19)	
			ACOEM Criteria	AHRQ USPSTF Criteria	ACOEM Criteria	AHRQ USPSTF Criteria
I. FACET JOINT INTERVENTIONS						
1. Lumbar intraarticular injections	Insufficient Evidence (I)	Not Recommended	NA	NA	NA	NA
2. Cervical intraarticular injections	Insufficient Evidence (I)	Not Recommended	NA	NA	NA	NA
3. Lumbar medial branch blocks	Insufficient Evidence (I)	Not Recommended	B	I	1B	1A
4. Cervical medial branch blocks	Insufficient Evidence (I)	Not Recommended	B	I	1B	1A
5. Thoracic medial branch blocks	NA	NA	B	I	1C	1B
6. Lumbar radiofrequency neurotomy	Evidence (C)	Not Recommended	B	I	1B or C	1B or C
7. Cervical radiofrequency neurotomy	Evidence (C)	Not Recommended	B	I	1B or C	1B or C
II. EPIDURAL INTERVENTIONS						
1. Blind caudal epidural steroid injections						
• *(Disc herniation & radiculitis)	Evidence (C)	Not Recommended	A	I	1A	1A
• (Post-laminectomy syndrome)	Evidence (C)	Not Recommended	B to C	II-1 to II-2	1C	1C
2. Blind lumbar interlaminar epidural injection	Evidence (C)	Not Recommended	1	II-2	2C	2A
3. Blind cervical interlaminar epidural injections	Insufficient Evidence (I)	Not Recommended	A	I	1A	1A
4. Lumbar transforaminal epidural injections	Evidence (C)	Not Recommended	A	I	1A	1A
5. Blind thoracic interlaminar epidural injections	NA	NA	NA	NA	NA	NA
III. SACROILIAC JOINT INTERVENTIONS						
1. Sacroiliac joint injections	Insufficient Evidence (I)	Not Recommended	1	NA	NA	NA
IV. ADHESIOLYSIS						
1. Percutaneous adhesiolysis	Insufficient Evidence (I)	Not Recommended	A	I	1A	1A
2. Spinal endoscopic adhesiolysis	Insufficient Evidence (I)	Not Recommended	B	I	1B	1A

A: strong evidence-base
B: moderate evidence-base
C: limited evidence-base
I: insufficient evidence

1A/strong recommendation, high-quality evidence
1B/strong recommendation, moderate quality evidence
1C/strong recommendation, low-quality or very low-quality evidence
*One study (275) was performed under fluoroscopy

Table 47 *Evidence synthesis comparison of intradiscal therapies and intraspinal implantables.*

Procedure	ACOEM Conclusions		Present Evaluation (Long-term only)			
	Strength of Evidence	Recommendation	Strength of Evidence		Recommendations Based on Guyatt et al's criteria (19)	
			ACOEM Criteria	AHRQ USPSTF Criteria	ACOEM Criteria	AHRQ USPSTF Criteria
V. INTRADISCAL THERAPIES						
1. Intradiscal electrothermal therapy	Insufficient Evidence (I)	Not Recommended	1	II-2	NA	2B
2. Percutaneous automated disc decompression	Evidence (B)	Moderately Not Recommended	C	II-2	NA	2B
VI. INTRATHECAL IMPLANTABLES						
1. Spinal cord stimulation						
• Post-lumbar laminectomy syndrome	Insufficient Evidence (I)	Not Recommended	A	I	1A	1A
• Complex Regional Pain Syndrome	Insufficient Evidence (I)	Not Recommended	1	II-3	2A	1C
2. Intrathecal implantable systems	N/A	N/A	NA	II-2	NA	1C

A: strong evidence-base
B: moderate evidence-base
C: limited evidence-base
I: insufficient evidence

1A/strong recommendation, high-quality evidence
1B/strong recommendation, moderate quality evidence
1C/strong recommendation, low-quality or very low-quality evidence

axonal transport of nerve fibers at lower concentrations compared with those that are necessary for a block of a nerve conduction (424,425). The long-lasting effect of local anesthetics on nerve blocks and epidural injections has been demonstrated in a multitude of previous studies, starting in early 1940's. Recently, the role of corticosteroids to produce additional benefit to nerve root infiltration for experimental disc herniation was evaluated (428). They concluded that no additional benefit from using corticosteroid was identified, suggesting that corticosteroid may be unnecessary for nerve root blocks. These authors (428) explained, on the basis of results of experimental investigation showing the increase in endoneural fluid pressure (EFP) with application of nucleus pulposus to the nerve root and a decrease of blood flow in thedorsal root ganglion, increased pressure by interference with capillary flow and interneural edema, followed by a breakdown of the myelin sheath and other cytoplasmic components of Schwann cells and the axon (429). Lidocaine reportedly reduces the increase in EFP and pathophysiological changes in the dorsal root ganglion induced by nucleus pulposus (430), and by improving EFP and blood flow in the dorsal root ganglion (431). In addition, lidocaine has been postulated to decrease acidosis by increasing blood flow (432) and interrupts the viscous cycle of pain by desensitizing the central and peripheral nervous systems by blocking abnormal impulses from and to the involved nerve root and dorsal root ganglion (433).

Corticosteroid anti-inflammatory properties have been described to relate to the inhibition of prostaglandin synthesis and decreases in regional levels or inflammatory mediators such as interleukin-1, tumor necrosis factor, and phospholipase A2 (409,411,434-436), by ameliorating early vascular permeability increases in spinal nerve roots and inhibiting reductions in nerve conduction velocity induced by epidural application of nucleus pulposus (437) and by exerting "anesthetic-like" actions on nociceptive C-fiber conduction independent of anti-inflammatory properties (409).

Lumbar Discography

Extensive information is provided showing the rationale for provocation discography, which is well established, including nerve supply, stimulation and pattern of referred pain, accuracy, and technique (59,64,107-114,125,126,438-451). Lumbar discography is helpful in patients with low back or lower extremity pain to acquire information about the structure and sensitivity of their lumbar intervertebral discs and to make informed decisions about treatment and modifications of activity. Major flaws in the ACOEM guidelines criticizing lumbar discography have been addressed in this manuscript. First, there is no requirement nor is it even recognized as desirable to perform diagnostic studies in a randomized, double-blind manner (47,99-102). Second, the authors failed to utilize their own accepted criteria (33) as shown in Table 5. Third, the authors of the ACOEM guidelines omitted the majority of the studies. Fourth, they have conducted systematic analysis of methodologic criteria improperly and included many of the scientifically controversial studies and excluded admissible and quality studies. Multiple flaws in these studies have been described in a systematic review (124). Interobserver agreement for lumbar discography has been demonstrated (128,129). Fifth, the technique of discography is standardized by both the IASP (106) and ISIS (107) and it has been well studied (59,64,107-114). Sixth, the accuracy of discography as an imaging test is high for the diagnosis of disc degeneration, and when reproducible, accurate and valid criteria are established. Thus, there must be at least one disc (preferably 2) that does not elicit pain upon injection, thereby serving as the control disc (59,64,106,107).

Assessment of the methodologic quality of lumbar discography studies (Table 11) shows variable results in the quality of the studies included in the ACOEM guidelines. The superiority of Carragee et al's studies (88,93-96,104,115) has not been established. Finally, valid reports have shown a prevalence of lumbar discogenic pain of 26% to 39% (125,126). Thus, the evidence resulting from reassessment of moderate to strong is appropriate and clinically applicable.

Above all, the major misunderstanding in the ACOEM guidelines has been false-positive rates of provocation discography. Apart from the description in the text, there are several other reasons for why a high false-positive rate may have been obtained in recent studies. First, as noted, all Carragee et al's studies used manual pressurization without dynamic pressure monitoring or control of speed of injection which may evoke pain in a non-pathologic disc (112). Second, Carragee et al's studies reported false-positive rates on a per patient instead of per disc basis. In 3 study populations (iliac crest pain, somatization disorder, and post-discectomy) (Table 10) this results in a significantly higher absolute number than if the data was presented per disc. It can be argued that the false-positive rate is best presented per disc, as provocation discography is designed as a per disc test to confirm or refute the hypothesis that the disc is the probable source of pain. As well, for treatment purposes, surgeons are interested in the number of pathologic disc levels. Third, Carragee et al's studies may have been biased towards a higher false-positive rate because of the subject population. All subjects, except the iliac crest pain and somatization disorder patients, had known symptomatic degenerative disc disease severe enough to require surgery. If the pre-test probability of disease (prevalence) is high, the positive predictive value (the likelihood that a patient with a positive discogram will have the disease) is also high. Carragee et al's subjects may have been asymptomatic with sub clinical or not yet symptomatic disease which was provocable with high pressurization and high dynamic intra-discal pressures. The literature suggests that co-existence of cervical and lumbar disc disease is common. Researchers posit a common genetic influence on disc degeneration. In MRI studies of twins, heritability for "severe disease" was 79% and 64% in the cervical and lumbar spine, respectively (452). In another study of 200 patients with severe cervical disc disease requiring surgery (mean follow-up of 14 years), 100% of the subjects reported significant episodes of back pain (suggestive of disc herniation) and/or underwent back surgery or had significant myelographic abnormalities (453).

Much of the controversy about discography has arisen because the results of discography have been used to help decide whether a certain patient should or should not have surgery, even though the patients have usually undergone other diagnostic tests, the results of which were either equivocal or non-diagnostic. Thus, discography should be performed only if the patient has failed to respond to adequate attempts at non-operative care, and if diagnostic tests such as MRI have not provided sufficient diagnostic information. Thus, specific uses for discography include, but are not limited to:

- Further evaluation of demonstrably abnormal discs to help assess the extent of abnormality or

correlation of the abnormality with clinical symptoms (in case of recurrent pain from a previously operated disc and a lateral disc herniation);
- Patients with persistent, severe symptoms in whom other diagnostic tests have failed to reveal clear confirmation of a suspected disc as the source of pain;
- Assessment of patients who have failed to respond to surgical procedures to determine if there is painful pseudoarthrosis or a symptomatic disc in a posteriorly fused segment, or to evaluate possible recurrent disc herniation;
- Assessment of discs before fusion to determine if the discs within the proposed fusion segment are symptomatic and to determine if discs adjacent to this segment are normal; and
- Assessment of minimally invasive surgical candidates to confirm a contained disc herniation or to investigate contrast distribution pattern before intradiscal procedures.

Thus, the consequence of the ACOEM guidelines in preventing discography as a diagnostic test will have serious consequences with an increase in costs not only the workers' compensation, but also of other insurers and federal and state governmental programs. Refusing discography as a diagnostic test may appear as a cost saving measure for workers' compensation system. However, when care is denied, at least some patients go through the legal system and get approved for fusions. This will result in higher proportion of fusions. If lumbar discography is utilized as an appropriate diagnostic test, discogenic pain is limited to 26% to 39% (125,126) instead of a majority of the patients who have disc degeneration. Further, an untoward consequence would be the responsibility of other insurers and governmental programs in paying for the care of these patients.

Reassessment with appropriate evidence synthesis showed the validity of lumbar provocation discography when performed as per IASP criteria. Further, the evidence for provocation discography is strong (A) based on the level of evidence criteria by ACOEM guideline criteria, whereas, it is Level I, based on AHRQ USPSTF criteria (Table 3) (21). The grade of recommendation is strong recommendation with 1A high-quality evidence, with benefits clearly outweighing risks and burdens, resulting in a strong recommendation which can apply to most patients in most circumstances without reservation.

Diagnostic Facet Joint Interventions

The ACOEM guidelines (33,34), with the combination of the low back pain and chronic pain chapters, describe facet joint interventions as diagnostic facet joint injections (intraarticular nerve blocks), therapeutic facet joint injections, facet joint hyaluronic acid injections, and radiofrequency neurotomy or facet rhizotomy. The evidence synthesis and recommendations are deficient in not only procedural guidance, but also in the inappropriate inclusion of all the regions of the spine and techniques available.

The ACOEM guidelines, similar to all other interventional techniques, utilized flawed methodology leading to inappropriate and inaccurate recommendations. The ACOEM guidelines criticize facet joint interventions on the basis of utilization of old, irrelevant, and flawed studies and narrative reviews. In addition to an inappropriate demand for randomized controlled trials, available randomized controlled trials were incorporated inappropriately in the assessment of diagnostic facet joint injections. Further, alleging the lack of evidence for accuracy of these interventions, the ACOEM guidelines have not recommended facet joint injections for diagnostic purposes in any type of condition.

Despite the extensive literature available on diagnostic facet joint nerve blocks, the authors have used inaccurate evidence and also methodology resulting in inaccurate conclusions and recommendations. They have utilized scientifically inadmissible studies and the claims resulted based on these studies (137,141-143). The rationale for facet joint blocks for diagnosis is based on the fact that facet joints are capable of causing pain and they have a nerve supply (144-155), neuroanatomic studies have demonstrated nerve endings and facet joints (156-159), spinal facet joints have been shown to be a source of pain in the various regions of the spine and upper and lower extremities (139,170-174) and facet joint pain has been shown to be prevalent based on controlled diagnostic blocks in accordance with criteria established by the IASP (106).

Reassessment of the evidence for facet joint nerve blocks showed high quality studies with strong evidence validating prevalence and false-positive rates and the techniques applied for the diagnosis (55,62,63,138,183-185,189-195,201-205). However, the controversies abound. Even the criticism appears to have been flawed (103,130,131). Review of Carragee et al's criticism on the validity of diagnostic facet joint nerve blocks appears to be invalid (103).

The reassessment shows the level of evidence for lumbar, cervical, and thoracic diagnostic facet joint nerve blocks is strong (A), utilizing either ACOEM's evidence basis or Level I, utilizing AHRQ USPSTF quality of evidence basis. Further, based on Guyatt et al's (19) grading criteria, the level of recommendation is 1A/ strong recommendation, high quality evidence, with benefits clearly outweighing the risks and burdens, with strong recommendation which applies to most patients in most circumstances without reservation.

Therapeutic Facet Joint Interventions

The ACOEM (33,34) guidelines described therapeutic facet joint injections to involve injections of a combination of a local anesthetic with glucocorticoids for the purposes of relieving pain from facet to facilitate an active therapy program or to maintain employment. The ACOEM guidelines also have described facet joint hyaluronic acid injections and radiofrequency neurotomy as a therapeutic facet joint intervention. However, the authors have not described all types of therapeutic interventions and have not included all regions in the analysis.

The ACOEM guidelines also described that these injections are performed as combined diagnostic and therapeutic injections, rather than first performing an anesthetic injection, followed by a second injection that includes the glucocorticoid steroid (33,132,133, 135,136,454). Further, they continued to state that this may also be accomplished either as an intraarticular as a pericapsular injection, using a number of techniques (142,143,455). They also described segmental rigidity as an indication for both diagnostic and therapeutic injections (137). The recommendation for therapeutic facet joint injections was that they are not recommended for chronic low back pain with strength of evidence as "insufficient evidence."

We performed a reassessment of the evidence synthesis by the ACOEM guidelines due to poor selection criteria as well as poor evidence synthesis by the authors of the ACOEM guidelines, utilizing a weighted scoring system. The ACOEM scores were higher for Carette et al's study (226) 73 vs 60, whereas for Fuchs et al's study (227) the scores were lower 63.7 vs 72. The study by Barnsley et al (228) was not utilized in the analysis which attained a score of 61. The results of the reassessment showed positive results for short-term relief of less than 6 months, whereas the results were not available for long-term relief after 6 months.

Reassessment of the evidence for lumbar intraarticular facet joint injections based on ACOEM guidelines is not available.

Evidence synthesis for medial branch blocks, which was not performed by the ACOEM guidelines, showed 3 quality studies evaluating therapeutic medial branch blocks in the cervical, thoracic, and lumbar regions with methodological quality scores of 68, 60, and 68. Overall, based on these randomized double-blind controlled studies with 1-year follow-up, results were positive for short-term and long-term, with moderate (B) evidence-based on ACOEM guideline synthesis criteria (Table 5) (33), whereas the evidence is Level I based on AHRQ USPSTF (Table 3) (21). Consequently, recommendations for medial branch blocks are 1A or 1B/strong recommendation is based on high or moderate quality evidence with benefits clearly outweighing the risks and burdens, with methodologic quality of supporting evidence derived from randomized controlled trials, with or without important limitations or evidence obtained from exceptionally strong observational studies, resulting in the implication that the recommendation can apply to most patients in most circumstances without reservation.

In the evaluation for radiofrequency neurotomy, the ACOEM guideline authors have utilized many scientifically inadmissible studies. However, in the reassessment only 3 studies met inclusion criteria and were assessed with methodological quality assessment. One of these (235) was not included in their evidence synthesis by the ACOEM guidelines, and the second study (262) was not published until 2008. The level of evidence is moderate (B) based on ACOEM criteria, Level I, based on AHRQ USPSTF criteria (Table 3) (21). for radiofrequency neurotomy of the cervical and lumbar medial branches. Based on Guyatt et al criteria (19), the recommendation is 1B or 1C/strong with moderate quality evidence, applicable in most patients in most circumstances, however which may be changed based on change in the evidence.

Epidural Injections

The ACOEM guidelines described that epidural glucocorticosteroid injections are performed in an attempt to deliver the active medication as close to the target tissue as possible, whether a herniated disc or spinal stenosis (56,456,457). The authors of the ACOEM guidelines also accurately describe that there are 3 approaches most commonly used: caudal, interlaminar, and transforaminal (54,56,86,458). However, they inaccurately described multiple issues and quoted inac-

curate references (54). They stated that the most commonly performed epidural is an interlaminar epidural injection in which the injection is placed immediately adjacent to the dural sac in the posterior spinal column with subsequent diffusion to the herniated disc or other offending structure. Fluoroscopic guidance has been shown to improve the accuracy of injection placement, since blind targeting has been shown to be less than 77% accurate (280) and quoted a transforaminal reference. They also reported that transforaminal injections most closely target the usual sites of pathology and inflammation and use the least volume of agent (33,280). Transforaminal epidural injections accomplish the same task as interlaminar, except the needle is placed along the nerve root in closer proximity to the herniated disc or impinged neurologic structure (33,34,56,459). Transforaminal injections were described as technically difficult and performed under fluoroscopy or CT guidance (33,34,460). These injections are considered to be diagnostic and therapeutic (33,460). Uncontrolled data suggest psychological factors may be associated with treatment failure, but that is not a universal finding (33,461). ACOEM guidelines (33) also concluded that there is no evidence for CT or MRI prior to performing any type of epidural injections (267,269,273). This is in contrast to various descriptions including the European Guidelines for the Management of Chronic Non-specific Low Back Pain and ACOEM guidelines own descriptions and the evidence illustrated by their own synthesis, which all dictate appropriate evaluation and differential response based on the diagnosis.

The ACOEM guideline evidence synthesis process has not provided an appropriate literature search, quality assessment, or inclusion of all spinal regions, and has not provided recommendations in connection with the available literature and the evidence. While they also mentioned 3 approaches, they have not evaluated the evidence based on 3 approaches. The 3 approaches which include caudal, interlaminar, and transforaminal possess substantial differences not only with reference to the technical aspects, but also in reference to cost, outcomes, and complications. The differences include the interlaminar entry is directed more closely to the assumed site of pathology, requiring lesser volume of injection than the caudal route. However, the caudal entry is relatively easily achieved, with minimal risk of inadvertent dural puncture. The transforaminal approach is target specific with the smallest volume of injection, fulfilling the aim of reaching the primary site of pathology, namely the ventral lateral epidural space. However, the complication rate is highest with transforaminal epidural injections and also varies with the region (lumbar vs thoracic vs cervical) (462-464). While, the ACOEM guidelines referenced the systematic reviews and other guidelines separating these 3 approaches and also the regions, they have ignored the evidence from these reviews. While many of the systematic reviews have been negative, Airaksinen et al (91) in preparation of European Guidelines for the Management of Chronic Nonspecific Low Back Pain concluded that the epidural corticosteroid injection should only be considered for radicular pain, if a contained disc prolapse is the cause of the pain and if the corticosteroid is injected close to the target. Further, they added that the injection should be fluoroscopically guided and should aim at the ventral part of the epidural space meaning a transforaminal approach.

It may be argued that scientific evidence supporting the efficacy of or lack thereof of one type of epidural in one region with or without fluoroscopy either indirectly supports or opposes the efficacy of epidural administration by any route of administration, performed with or without fluoroscopy, with or without steroids. This argument may make sense in view of the anatomy of the epidural space, the pathophysiology of radiculopathy, the application of inappropriate standards, and utilizing a political agenda. However, the epidural space is a continuous anatomic compartment extending from the base of the skull to the sacrum that can be entered at various levels and by various routes to achieve the same result. The space itself consists of adipose tissue interspersed with random bands of fibrous tissue and veins. The ventral epidural space is closest to the posterior disc margin and the traversing nerve root, which is the presumed site of pathology in lumbar radiculopathy (56). Although, the most direct method to deposit medication into this region is by using a transforaminal approach to needle insertion under fluoroscopic visualization, it is conceivable that medication may reach this target almost equally using a caudal or interlaminar route of administration or with catheterization. However, the results of all the studies and the present reassessment show otherwise.

Our reassessment utilizing appropriate criteria and grading recommendations shows results different from the ACOEM guidelines. Based on this reassessment, caudal epidural injections, cervical interlaminar epidural injections, and lumbar transforaminal epidural injections present with strong evidence (A)

and Level I, for short-term and long-term relief of 6 months or longer with 1A/strong recommendation, utilizing Guyatt et al's (19) criteria with application in most cases.

Contrary to the above, there was no evidence available for thoracic epidural injections and the evidence for lumbar interlaminar epidural injections is Level II-2 to insufficient.

Thus, epidural steroid injections are recommended in lumbar region, either with caudal or transforaminal approach under fluoroscopy, whereas, cervical interlaminar epidurals are recommended for neck pain.

Sacroiliac Joint Interventions

The sacroiliac joint is a synovial joint with abundant innervation and the capability of being a source of low back pain and referred pain in the lower extremity (316-318,465-479). The sacroiliac joint has been shown to be a source of pain in 10% to 26.6% of suspected cases (126,314,315). The literature has shown that sacroiliac joint pain may be managed by intraarticular injections and neurolysis of the sacroiliac joint. The evaluation of the effectiveness of intraarticular sacroiliac joint injections and radiofrequency neurotomy of nerve supply has consistently shown that there was no significant evidence for therapeutic intraarticular injections or radiofrequency neurotomy from evidence derived from randomized trials.

The reassessment showed significant evidence for diagnostic blocks of sacroiliac joints. However, there was no evidence for therapeutic facet joint interventions.

Percutaneous Adhesiolysis

The ACOEM guidelines (33) describe epidural adhesiolysis as a relatively new technique that attempts to address adhesions that particularly develop after surgery and are proposed by some to be related to post-operative pain and the "failed back surgery syndrome" (33,347). The ACOEM guidelines describe that epidural adhesiolysis is also known as percutaneous lysis of epidural adhesions, epidural neurolysis, epidural decompressive neuroplasty, and Racz neurolysis (33,69,347). The description includes that this procedure involves injection of hypertonic saline to attempt to address the adhesions that may be present (33). A catheter is used to enter the epidural space through a caudal, interlaminar, or transforaminal approach (33). An anesthetic and sometimes hyaluronidase, along with glucocorticosteroid, are also injected (33). There are 1 and 3 day protocols. These procedures may also involve spinal endoscopy to visually address adhesions (33,348).

Percutaneous epidural adhesiolysis or lysis of epidural adhesions or epidural adhesiolysis with a spinal endoscope (myeloscope or epiduroscope) are interventional pain management techniques that play an active role in managing chronic intractable low back pain and/or lower extremity pain (58,68,347-353,480,481). It is postulated that epidural lysis of adhesions minimizes the deleterious effects of epidural scarring, which can physically prevent the direct application of drugs to nerves and other spinal tissues and manages chronic back and lower extremity pain (58,68). In addition, epidural lysis of adhesions and direct deposition of corticosteroids in the spinal canal can also be achieved with a 3-dimensional view provided by epiduroscopy or spinal endoscopy - a distinctly separate procedure with separate codes and indications compared to percutaneous adhesiolysis which is catheter based.

The ACOEM guidelines erred in the evidence synthesis by eliminating multiple studies which were appropriately performed according to CONSORT criteria (482). Further, the study by Dashfield et al (275) studied the endoscopic delivery of steroids or caudal epidural steroid injections in patients without adhesions, not meeting the inclusion criteria, which is basically clear that to perform adhesiolysis, that patient must have adhesions and is non-responsive to other modalities of treatments including fluoroscopically directed caudal epidural steroid injections.

Based on the reassessment, the results are different. Further, the ACOEM guideline synthesis process with 11 items given equal weight, were shown to be flawed with ACOEM's assessment scores of 72.8, 22.75, and 45.5, compared to reassessment scores of 69, 64, and 50. In addition, strong evidence (A) is demonstrated for percutaneous adhesiolysis and moderate (B) for endoscopic adhesiolysis based on ACOEM guideline synthesis (33) and Level I, based on AHRQ USPSTF criteria (Table 3) (21). Further, as per Guyatt et al's (19) grading strength of recommendation of strong, 1A or 1B/strong recommendation with high or moderate quality evidence with benefits clearly outweighing the risks and burdens, with methodologic quality of supporting evidence from randomized controlled trials, with or without important limitations, with implications of the strong recommendation which can apply to most patients in most circumstances without reservation.

Intradiscal Therapies

The ACOEM guidelines (33) described IDET as involving the heating of an intradiscal probe through electrical current with a proposed goal of coagulating tissue and theoretically resulting in improvement in pain thought to be derived from the disc or surrounding structures (483-485). The guidelines also commented on percutaneous intradiscal radiofrequency thermocoagulation (PIRFT).

Minimally invasive procedures promoted as alternatives to the major surgical intervention involves the introduction of a flexible electrode into the painful disc, with the aim of coagulating the posterior annulus (1). The pathologic basis for some forms of low back pain may lie in internally disrupted intervertebral discs and in particular, sensitized annular tears (444-451,486-490). Multiple treatments described to manage internal disc disruption and discogenic pain include surgical intervention with total disc excision and arthrodesis or conservative measures such as intradiscal steroid, chemonucleolysis, intradiscal glycerol, and the use of intradiscal laser devices. IDET is one of the most commonly performed procedures for intradiscal therapy.

Thus, the evidence assessment by the authors of the ACOEM guidelines is at best borderline, excluding systematic reviews (70-74) and other evidence typically utilized in guideline preparation (1). In an appropriate analysis, systematic reviews take the highest priority. Since there are an equal number of positive systematic reviews (71,72) providing moderate evidence than negative ones (73,74), the moderate evidence is appropriate, specifically considering that IDET is much less expensive than fusion and disc replacement. Since these guidelines (33) eliminate discography as a valid diagnostic test, and they also eliminate IDET as a viable therapy, patients will no doubt receive more intradiscal disc prostheses and fusions through appeals, court decisions, and other avenues.

Based on the reassessment, utilizing the strict criteria of randomized trials and ACOEM guideline (33) synthesis, the evidence is insufficient (1). However, utilizing the criteria developed by AHRQ (21), the evidence for IDET appears to be Level II-2 in managing chronic discogenic low back pain. Consequently, based on Guyatt et al's (19) criteria, the recommendation is 2B/weak recommendation with moderate quality evidence, with benefits closely balanced with the risks and burdens; nevertheless, best action differing depending on circumstances of patients' or societal values.

Percutaneous Disc Decompression

Studies of asymptomatic adults commonly demonstrate intervertebral disc herniations that apparently do not cause symptoms (33). There is no quality evidence that delaying surgery for this period worsens outcomes in the absence of progressive nerve compromise (33,491). The ACOEM guidelines (33) also describe that with or without surgery, more than 70% of patients with apparent surgical indications eventually recover to the pre-morbid activity level including those with severe initial presenting signs of neurological compromise (490,592). Spine surgery for patients with clear indications appears to speed short- to mid-term recovery (33). However, surgery results in improvements in pain in fewer than 40% of patients with questionable physiologic findings, which is the rate of response of pain to placebo surgery (33,493,494). Moreover, surgery statistically increases the risk for future spine procedures, with higher complication rates (33). In older patients and repeat procedures, the rate of complications is dramatically higher. Patients with comorbid conditions, such as cardiac or respiratory disease, diabetes, or mental illness, may be poor candidates for surgery (33). Consequently, the ACOEM guidelines (33) recommend a referral for surgical consultation for patients who have:

- Severe and disabling lower leg symptoms (radiculopathy) in a distribution consistent with abnormalities on imaging studies, preferably with accompanying objective signs of neural compromise;
- Activity limitations due to radiating leg pain for more than 4 to 6 weeks;
- Imaging evidence of a lesion (disc herniation, spinal stenosis, spondylolisthesis) with clear clinical correlation to the patient's symptoms and physical findings (at the correct level and on the correct side); and
- Failure of time and an adequate trial of conservative treatment generally including epidural glucocorticosteroid injection(s) to resolve disabling radicular symptoms.

The ACOEM guidelines also recommend that physicians may consider referral for psychological screening to improve surgical outcomes, possibly including standard tests such as the MMPI and non-organic signs (e.g., Waddell) during physical exam, as these have been shown to correlate with poorer surgical outcome

(33). Fishbain et al (495), in a systematic review, based on 57 studies, concluded that Waddell's Signs:

1) Do not correlate with psychological distress
2) Do not discriminate organic from nonorganic problems
3) May represent an organic phenomenon
4) Are associated with poorer treatment outcome
5) Are associated with greater pain levels
6) Are not associated with secondary gain
7) Waddell's sign studies, as a group, demonstrate some methodological problems.

Fishbain et al (496) in another review concluded that there was little evidence for the claims of an association between Waddell's signs and secondary gain and malingering. They also concluded that the preponderance of evidence points to the opposite — no association (495-503).

However, the presence of non-organic signs has been highly controversial (495-509). The presence of Waddell's signs has been thought to indicate psychologic distress (498,499), a more magnified or more emphatic presentation of the severity of their problem (498), to indicate the possibility of abnormal illness behavior (498), described as maladaptive overt illness-related behavior which is out of proportion to the underlying physical disease and more readily attributable to the associated cognitive and affective disturbance (500), have been equated with pain behavior (500), and somatic amplification (501), leading to descriptions of malingering or pain of psychologic origin (502,503). Waddell signs are listed as one of the widely used methods to determine sincerity of effort (497). Gallagher (509) in an editorial objectifying pain and the limits of medical altruism about Waddell Signs described that they were proposed in a climate of uncertainty about the proper treatment of chronic back pain. Gallagher (509) described that like many new tests and treatments that promise great benefit for pain, the use of Waddell's Signs since 1990 has been controversial because of their overuse for purposes not intended by Waddell and colleagues. While Waddell's signs may have been at the cutting edge in 1980, understanding of pain processing, sensitization, and modulation through neuroscience and imaging, the misuse and abuse of Waddell Signs have been pointed out. Further, Waddell and colleagues have consistently cautioned against over-reliance on and misplaced use of signs or symptoms.

Influence of psychological factors on the outcomes of surgery also have been controversial (510-514). Thus, ACOEM guidelines have utilized inappropriate evidence with non-organic signs and influence of psychological factors. They reached conclusions without analyzing the evidence.

Based on the reassessment of the evidence for automated percutaneous lumbar discectomy (APLD) derived from randomized trials, the evidence is limited (C) by ACOEM critiera (33). However, utilizing AHRQ evidence-based criteria, the evidence for automated percutaneous disc decompression is Level II-2, with 2B/weak recommendation as described by Guyatt et al's (19) criteria.

Spinal Cord Stimulation

The ACOEM guidelines provided evidence and recommendation conflicting with the available evidence and multiple systematic review (78-83), and have not recommended spinal cord stimulation for any type of pain due to insufficient evidence except in rare circumstances for short-term or intermediate-term relief.

Reassessment of evidence utilizing only randomized controlled trials yielded strong evidence for failed back surgery syndrome based on an evidence base described by ACOEM guidelines (33) and Level I as per AHRQ USPSTF level of evidence (Table 3) (21). However, the evidence for CRPS is insufficient (1), based on ACOEM evidence synthesis, and Level II-3, based on AHRQ USPSTF evidence base (21), with a 1C to 2A recommendation. Based on Guyatt's criteria (19), recommendation is strong 1A or 1B for failed back surgery syndrome.

Intrathecal Infusion Systems

ACOEM guidelines have not described the role of intrathecal infusion systems and as such have not evaluated the evidence and mentioned them as "pain pumps" (34). The evidence assessment in this evaluation found no randomized trials evaluating long-term use of intrathecal implantable infusion systems for chronic non-cancer pain; however, based on AHRQ criteria (21), Level II-2 evidence is assessed along with recommendation of 1C/strong recommendation based on observational studies.

Conclusion

The reassessment and reevaluation of the low back pain and chronic pain chapters of the ACOEM guidelines (33,34) presents results that are much different from the published and proposed guidelines. Based on the reevaluation with utilization of only

randomized trials for therapeutic interventions and appropriate utilization of diagnostic studies, vastly different results were found in this evaluation. Thus, significant differences in strength of rating for the diagnosis of discogenic pain by provocation discography, facet joint pain by diagnostic facet joint nerve blocks, and sacroiliac joint pain by diagnostic sacroiliac joint nerve blocks were identified. Similarly for therapeutic techniques, therapeutic cervical medial branch blocks and radiofrequency neurolysis, cervical interlaminar epidural steroid injections, caudal epidural steroid injections, lumbar transforaminal epidural injections, spinal cord stimulation and percutaneous adhesiolysis significant differences were identified. Further, the evidence rating for intrathecal infusion systems, IDET and automated percutaneous disc decompression is different.

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