Final Topic Refinement Document
Pain Management Injection Therapies for Low back Pain – Project ID ESIB0813

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Topic: Pain Management Injection Therapies for Low-back Pain

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Key Questions

Key Question 1. In patients with low back pain, what characteristics predict responsiveness to injection therapies on outcomes related to pain, function, and quality of life?

Key Question 2. In patients with low back pain, what is the effectiveness of epidural corticosteroid injections, facet joint corticosteroid injections, medial branch blocks, and sacroiliac joint corticosteroid injections versus epidural nonsteroid injection, nonepidural injection, no injection, surgery or non-surgical therapies on outcomes related to pain, function and quality of life?

Key Question 2a. How does effectiveness vary according to the medication used (corticosteroid, local anesthetic, or both), the dose or frequency of injections, the number of levels treated, or degree of provider experience?

Key Question 2b. In patients undergoing epidural corticosteroid injection, how does effectiveness vary according to use of imaging guidance or route of administration (interlaminar, transforaminal, caudal, or other)?

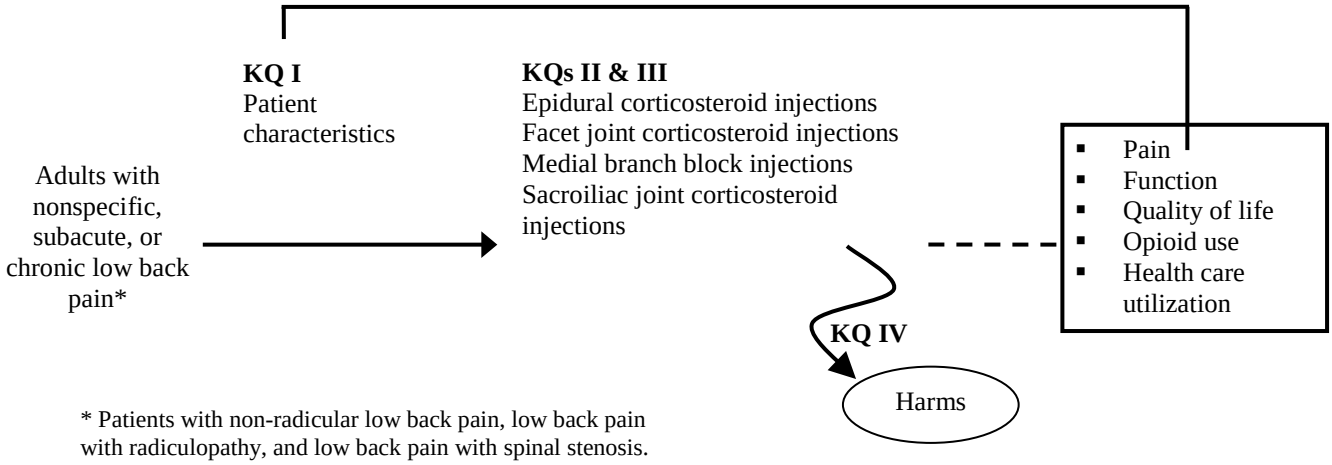
Key Question 3. In randomized trials of low back pain injection therapies, what is the response rate to different types of control therapies (e.g., epidural nonsteroid injection, nonepidural injection, no injection, surgery, or non-surgical therapies)?

Key Question 3a. How do response rates vary according to the specific comparator evaluated (e.g., saline epidural, epidural with local anesthetic, nonepidural injection, no injection, surgery, non-surgical therapies)?

Key Question 4. What are the harms of epidural corticosteroid, facet joint corticosteroid injections, medial branch blocks, and sacroiliac joint corticosteroid injection compared to epidural nonsteroid injection, nonepidural injection, no injection, surgery, or non-surgical therapies?

Analytic Framework

Analytic Framework for Pain Management Injection Therapies for Low-back Pain



* Patients with non-radicular low back pain, low back pain with radiculopathy, and low back pain with spinal stenosis.

Background

Low back pain is one of the most frequently encountered conditions in clinical practice. Up to 84 percent of adults have low back pain at some time in their lives, and a national survey of US adults in 2002 found that over one-quarter reported low back pain lasting at least a whole day in the past 3 months.[1, 2]Although low back pain affects persons of all ages, its prevalence peaks at 55 to 64 years of age and remains common in persons 65 years of age and older.[3] Low back pain can have major adverse impacts on quality of life and function and is frequently associated with depression or anxiety. Low back pain is also costly. In 1998, total US health care expenditures for low back pain were estimated at $90 billion.[4] Since that time, costs of low back pain care have risen substantially, and at a rate higher than observed for overall health expenditures.[5] Low back pain is one of the most common reasons for missed work or reduced productivity while at work, resulting in high indirect costs; this makes the total costs associated with low back pain substantially higher than the direct health care costs.[6]

The prognosis of acute low back pain (an episode lasting less than 4 weeks) is generally favorable. Following onset of low back pain, most patients experience a rapid improvement in (and often a complete resolution of) pain and disability and are able to return to work.[7] In those with persistent symptoms, continued improvement is often seen in the subacute phase between 4 and 12 weeks, though at a slower rate than observed in the first few weeks. In a minority of patients, low back pain lasts longer than 12 weeks, at which point it is considered chronic, and levels of pain and disability often remain relatively constant.[8] Such patients account for the bulk of the burdens and costs associated with low back pain.[9, 10]

In the majority (>85 percent) of patients with low back pain, symptoms cannot be attributed to a specific disease or spinal pathology.[11] Spinal imaging abnormalities such as degenerative disc disease, facet joint arthropathy, and bulging or herniated intervertebral discs are extremely common in patients with low back pain, particularly in older adults. However, such findings poorly predict the presence or severity or low back pain.[12] Radiculopathy from nerve root impingement and spinal stenosis (narrowing of the spinal canal) each occur in about 4 to 5 percent of patients with low back pain and can cause neurological symptoms such as lower extremity pain, paresthesias, and weakness.[13, 14]

Multiple treatment options for subacute and chronic low back pain are available. Broadly, these can be classified as pharmacological treatments,[15] non-pharmacological treatments (e.g., exercise therapy, cognitive behavioral therapy, spinal manipulation, acupuncture, and others),[16] injection therapies,[17] and surgical treatments.[18] Injection therapies, the topic of this evidence review, include injections of medications to various structures in and around the spine (such as the epidural space, facet joints, intervertebral discs, and soft tissues) or the application of various types of energy to ablate pain-generating nerves.[17] The most commonly used medications in back injections are corticosteroids to reduce inflammation and local anesthetics for analgesia, though others (such as anti-tumor necrosis factor agents, methylene blue, and ozone) have also been studied. Ablative therapies include radiofrequency denervation, intradiscalelectrothermal therapy, percutaneous intradiscal radiofrequency thermocoagulation, and other procedures.

Between 1994 and 2001, use of epidural injections increased by 271 percent and facet joint injections by 231 percent among Medicare beneficiaries.[19] Total inflation-adjusted reimbursed costs (based on professional fees only) increased from $24 million to over $175 million over this time period. More recent data indicate continued rapid growth in use of spinal injection therapies among Medicare beneficiaries, with an increase of 187 percent in use between 2000 and 2008.[19]

Despite these dramatic increases, use of injection therapies for low back pain remains controversial. Systematic reviews of injection therapies have come to conflicting conclusions regarding the benefits of injection therapies,[17, 20-27] and clinical practice guidelines provide discordant recommendations regarding their use.[28-34] Important challenges in conducting a review of this topic include sparse data from randomized trials for most injection therapies (with the exception of epidural steroids), inconsistency of results across trials, as well as variability across studies in the methods used to select patients for inclusion, the specific techniques used, the comparisons evaluated, and the outcomes assessed.[17] Methods for patient selection are critical because injection therapies are targeted at specific structures presumed to be causing pain within the spine, such as the intervertebral disc (discogenic back pain) or facet joint (facet joint pain). However, diagnostic methods for determining the source of pain differ across studies, and their accuracy cannot be determined due to a lack of reliable reference standards. Together, these factors could introduce heterogeneity, and make it difficult to determine whether negative results in a given trial are due to suboptimal patient selection, an ineffective therapy, or some combination of both factors.[17] Another source of potential heterogeneity is variability in injection techniques. For example, trials of facet joint radiofrequency denervation vary in the duration and intensity of the ablative therapy, as well as in the specific anatomic site where it is applied.[17] Among trials of epidural corticosteroid injections, there has been variability in methods used to approach the epidural space (e.g., interlaminar, transforaminal, or caudal), the use of fluoroscopic guidance, the volume of injectate administered, and the specific corticosteroid and dose used.[23] In addition, trials have compared an epidural corticosteroid injection to an epidural saline injection, epidural injection of local anesthetic without corticosteroid, a soft tissue injection, or no injection.[35] Another challenge is that trials of injection therapies have frequently focused on short-term outcomes related to pain, rather than longer term functional outcomes.

Given the continued growth in use of injection therapies for low back pain and continued uncertainty regarding their role and optimal use, a systematic review to summarize the current state of evidence, identify and evaluate inconsistencies in the evidence, and identify important research gaps is warranted to help inform clinical practice and policy.

PICOTS

Population(s):

Include:

- For all Key Questions: Adults with subacute (4 to 12 weeks) or chronic (>12 weeks) symptoms of the following:
    - For epidural corticosteroid injections- Non-radicular low back pain, low back pain with radiculopathy, or spinal stenosis
    - For facet joint corticosteroid injection and medial branch block- Non-radicular low back pain;
    - For sacroiliac joint corticosteroid injection- Non-radicular back pain in the sacroiliac region

Exclude:

- Persons younger than 18 years of age

Interventions:

Include:

- All Key Questions: Epidural corticosteroid injection, facet joint corticosteroid injection, medial branch block, sacroiliac joint corticosteroid joint injection

Exclude:

- Intraspinal injections involving anti-tumor necrosis factor agents, radiofrequency denervation, intradiscal electrothermal therapy, chemonucleolysis, and intradiscal methylene blue or ozone

Comparators:

Include:

- For Key Question 1: Studies that evaluate the effects of patient characteristics (e.g., age, sex, duration of pain, pain level, expectations of treatment benefits, confidence in clinician, worker's compensation status, ongoing litigation, smoking status, or other treatment received) or findings with interventional diagnostic techniques (e.g., discography, selective nerve root block, facet joint block, medial branch block, sacroiliac joint block), imaging studies, and/or other clinical criteria.
- For Key Questions 2, 3, and 4: Saline epidural, epidural with local anesthetic, nonepidural injection, no injection, surgery, or non-surgical therapies.

Exclude:

- Uncontrolled or pre-post studies

Outcomes:

Include:

- For Key Questions 1 2, 3: Pain, function, quality of life, opioid use, subsequent surgery, health care utilization
- For Key Question 4: Harms, including bleeding, infection, neurological events, and systemic complications, such as weight gain, diabetes, osteoporosis, and other endocrinological effects

Timing:

Include:

- For all Key Questions: Outcomes measured 1 week or later after the injection; durability of treatment response will be assessed

Study Designs:

- For Key Questions 1-3: Randomized controlled trials
- For Key Question 4: Randomized controlled trials or controlled cohort studies

Settings:

Include:

- For all Key Questions: No restrictions

Definition of Terms

Epidural corticosteroid injections: Injection of corticosteroids via a catheter into the space between the dura and the spine. Common approaches for administering epidural steroid injections are through the interlaminar space, via the neuroforamen under fluoroscopic guidance (transforaminal), and through the sacral hiatus at the sacral canal (caudal).

Facet joint corticosteroid injections: Injection of corticosteroid into the facet joints.

Medial branch block injections: Injection of local anesthetic with or without corticosteroid in the area of the medial branch of the posterior primary ramus, the primary nerve innervating the intervertebral facet joint. Usually used as a diagnostic procedure to identify facet joint pain, but has also been used as a therapeutic procedure.

Sacroiliac joint corticosteroid injections: Injection of corticosteroid into or around the sacroiliac joint.

Changes to the Key Questions and Scope as a Result of Public Comment

The draft research plan for this topic was posted for public comment from February 14, 2014 through March 3, 2014. In response to public comments, the Key Questions were revised to be more inclusive of various imaging guidance techniques, provider experience was added as a potential modifier of treatment effect, and the Analytic Framework was revised to be clear that non-surgical therapies are a comparator.

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