*Transport Accident Commission & WorkSafe Victoria*

*Evidence Service*

# Spinal Injection Therapies: Epidural Injections

## Evidence Review

## April 2009

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## CONTENTS



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## SPINAL INJECTION THERAPIES: EPIDURAL INJECTIONS

**PLAIN LANGUAGE SUMMARY**

The nerves from the brain to the body run down a canal inside the backbone. The bones surround and protect the nerves. The space between the nerves and the bones is called the epidural space.

Injections into the epidural space have been used to treat patients for persistent neck and back pain. Usually steroid and local anaesthetic are used.

This report looked at research studies to see whether epidural injections are safe and useful.

Some research studies are specifically designed to test whether a treatment is helpful or not and the results are trustworthy. These studies are called high level evidence. Other studies are not designed to test the treatment, but just observe what happened to patients who received it or to those who did not. These studies can provide some information, but it is not as certain as the information from high level evidence. These studies are referred to as low level evidence, sometimes called observational studies.

### 1. Cervical epidural injections

Cervical relates to the neck.

One relevant guideline that assessed the usefulness of cervical epidural injections for whiplash-associated neck pain was found. Guidelines are written by a group of specialists and based on research. This guideline was unable to identify any research. This does not mean that cervical epidural injections are not helpful, it just means that no research studies have proven that they are.

A report that looked at the complications of cervical epidural injections found that there were no major problems. Side effects occurred in a small number of patients. The authors decided that care and caution were needed when doing cervical epidural injections.

### 2. Thoracic epidural injections

Thoracic relates to the upper back.

No relevant studies that assessed the usefulness of thoracic epidural injections for upper back pain were found. This does not mean that these injections are not helpful; it just means that no research studies have proven that they are.

### 3. Lumbar epidural injections

Lumbar relates to the lower back.

One good quality trial had inconsistent results. Immediately after treatment, patients who had injections of steroids plus local anaesthetic had more relief of leg pain than those who did not. There was no difference in back pain. At three months there was no difference in leg pain but back pain was worse in the patients who had the treatment. By six months both leg and back pain were worse in those who had the treatment. One year after treatment there was no difference between the two groups.

The patients who had injections of steroids plus local anaesthetic had better function three months after treatment than those who did not. There was no difference in function between the two groups one year after the injections.

There was no difference in quality of life, sick leave, use of medication or use of health care services between the two groups up to one year after treatment.

A report that looked at complications of lumbar epidural injections found that there were no major complications. Side effects occurred in a small number of patients. The authors decided that care and caution were needed when performing epidural injections.

## SPINAL INJECTION THERAPIES: EPIDURAL INJECTIONS

**EVIDENCE SUMMARY**

Epidural injections have been used to treat patients for chronic spinal pain and are known by many names, including spinal nerve root sleeve injection, spinal nerve root injection, spinal nerve root block, periradicular infiltration, perineural injection, dorsal root ganglion nerve injection, dorsal root ganglion injection or dorsal root ganglion block.

Radiological guidance (including fluoroscopy, computed tomography, magnetic resonance imaging and ultrasound) is used to verify the correct location of the injection, so that the affected area of the spinal nerve is directly targeted. It is thought that the majority of therapeutic benefit of epidural injections is from the anti-inflammatory effects of corticosteroids. Anaesthetic agents are also thought to have a beneficial effect by reducing painful muscle spasm. Therefore, in this report steroid and local anaesthetic are included as an intervention either alone or in combination with each other. Both steroid and local anaesthetic are consequently excluded as a control.

# 1. Cervical epidural injections

### General comment

One relevant good quality evidence-based guideline that addressed the effectiveness of cervical epidural injections for whiplash-associated pain was identified; however this guideline did not find any evidence. A systematic review that addressed complications of epidural injections was also identified but the information available is based on observational studies only.

### In what conditions is this intervention indicated?

The authors of the guideline did not specify any patient groups/conditions for which this intervention is indicated.

### What is the effectiveness of this intervention on pain in these conditions?

There is insufficient evidence available to provide any information on effectiveness of cervical epidural injections for pain.

### What is the effect of this intervention on function, quality of life, return to work, medication use and healthcare utilisation?

There is insufficient evidence available to provide any information on effectiveness of cervical epidural injections for function, quality of life, return to work, medication use or health care utilisation.

### In what patient groups/conditions is this intervention contraindicated?

The authors of the guideline did not specify any patient groups/conditions for which this intervention is contraindicated.

### What are the risks associated with use of this intervention?

There is insufficient evidence available to provide specific information about the risks of cervical epidural injections, however the systematic review noted that they may be associated with complications and adverse events and recommended that attention to detail and caution should be practiced in order to improve safety and minimise complications.

# 2. Thoracic epidural injections

No relevant studies that evaluated the effectiveness of thoracic epidural injections for back pain were identified. Therefore we conclude that there is no evidence of effectiveness of this intervention.

## 3. Lumbar epidural injections

### General comment

The evidence of effectiveness of lumbar epidural injections comes from one well conducted randomised controlled trial (level II). A systematic review that addressed complications of epidural injections was also identified but the information available is based on observational studies only.

### In what conditions is this intervention indicated?

No specific indications for use were identified. Lumbar epidural injections were undertaken on adult patients with sciatica who have unilateral symptoms of one to six months and in patients with chronic spinal pain (axial and radicular) in the low back region.

### What is the effectiveness of this intervention on pain in these conditions?

One good quality RCT had inconsistent results. Immediately after treatment and again two weeks later, patients who received injections of steroids plus local anaesthetic had greater improvement in leg pain than those who had saline injections, but there was no difference between the intervention and control groups for back pain. At three months there was no difference in leg pain between the two groups but back pain was worse in the patients who had the intervention. By six months both leg and back pain were worse in the steroid plus local anaesthetic group. One year after treatment there was no difference between the two groups.

Based on these findings, the evidence of effectiveness for lumbar epidural injections is inconclusive.

### What is the effect of this intervention on function, quality of life, return to work, medication use and healthcare utilisation?

There is level II evidence that lumbar epidural injections with steroids plus local anaesthetic may be more effective than saline injections for improvement in function up to three months after treatment. By one year, there was no difference.

There is level II evidence that lumbar epidural injections with steroids plus local anaesthetic are not significantly different from saline injections for patient satisfaction, sick leave, and costs for medication and healthcare utilisation.

### In what patient groups/conditions is this intervention contraindicated?

The authors of the RCT did not specify any patient groups/conditions for which this intervention is contraindicated.

### What are the risks associated with use of this intervention?

There is insufficient evidence available to provide specific information about the risks of lumbar epidural injections, however the systematic review noted that they may be associated with complications and adverse events and recommended that attention to detail and caution should be practiced in order to improve safety and minimise complications.

# Spinal Injection Therapies: Epidural Injections

# Evidence Review

# April 2009

Marie Misso, Jane Reid, Claire Harris

## BACKGROUND

Spinal injection therapies have been used to treat patients with pain arising from the neck, back and sacroiliac joints. These interventions include epidural injections, medial branch blocks, facet joint injections and sacroiliac joint injections.

In order to develop and update policies for the use of spinal injection therapies in patients with pain the Health Services Group of the Transport Accident Commission and WorkSafe Victoria (TAC/WSV) requested a systematic review of the evidence of effectiveness of these interventions.

A preliminary scoping exercise identified numerous evidence resources related to spinal injection therapies. Several high level studies such as evidence-based guidelines (EBGs), systematic reviews and health technology assessments (HTAs) were available for a number of the interventions, randomised controlled trials (RCTs) were available for some interventions, and others had no studies identified. In light of the complexity of the research questions and the multiple sources of information available, this review was undertaken in a two-stage process. Due to differences in clinical approach and the patient populations, TAC/WSV requested that epidural injections be reviewed separately to the other interventions.

Unlike other spinal injection therapies, which are usually reserved for patients with chronic or persistent pain, epidural injections are also used in patients with acute pain. They are known by many names, including spinal nerve root sleeve injection, spinal nerve root injection, spinal nerve root block, periradicular infiltration, perineural injection, dorsal root ganglion nerve injection, dorsal root ganglion injection or dorsal root ganglion block. Epidural injections are used across a variety of spinal locations (cervical, thoracic and lumbar) and are administered via three main approaches (caudal, interlaminal and transforaminal).

It is thought that most of the therapeutic benefit from epidural injections is due to the anti-inflammatory effects of corticosteroids [1]. Local anaesthetics are also thought to have a short term beneficial effect by reducing painful muscle spasm [1]. For the purposes of this review, steroids and local anaesthetics, either alone or in combination, are considered to be interventions when given by epidural injection. Consequently, studies using steroids and/or local anaesthetics as comparators are excluded.

Radiological guidance including fluoroscopy, computed tomography, magnetic resonance imaging and ultrasound is used to verify the correct location of the injection, so that the affected area of the spinal nerve is directly targeted. [2]

## QUESTIONS

This review was undertaken as a two-stage process addressing the following questions. Details of this process are contained in Appendix 1.

### Stage 1: Identification of the best available evidence

Is synthesised evidence available (eg. EBGs, systematic reviews, HTAs)?

Is the available synthesised evidence of good quality?

Is the available good quality synthesised evidence current (within 2 years)?

Does the current, good quality synthesised evidence contain controlled trials?

Are there any controlled trials available for these interventions?

Based on the available evidence, what further action is recommended to address the questions in Stage 2?

### Stage 2: Assessment of the interventions based on the best available evidence

In what conditions is this intervention indicated?

What is the effectiveness of this intervention on pain in these conditions?

What is the effect of this intervention on function, quality of life, return to work, medication use and healthcare utilisation?

In what patient groups/conditions is this intervention contraindicated?

What are the risks associated with use of this intervention?

## METHODS

Methods used for each stage are outlined briefly below with detailed information available in appendices.

### Stage 1: Identification of the best available evidence

#### Systematic approach

Standard systematic review methodology was used to identify existing synthesised research (eg. EBGs, systematic reviews and HTAs) and any available comparative studies (eg. RCTs, controlled trials and cohort studies). Selection criteria were established *a priori*. A comprehensive search of the internet, relevant websites and electronic health databases was undertaken. Standard criteria for assessment of validity were applied. Details of the systematic review methods are included in Appendix 2.

A systematic review of facet joint injections and medial branch blocks was conducted concurrently with this review. The database and internet searches were undertaken together and application of inclusion and exclusion criteria was conducted on the combined dataset.

#### Evidence Map

For each anatomical location, a list of synthesised research and primary studies that fulfilled the selection criteria was prepared. The most up-to-date source of evidence was selected and appraised for quality. Once the most recent source of high quality evidence was identified, it was then compared with the other publications for scope and consistency of findings. Recommendations for Stage 2 were developed. Details of the Evidence Map and Recommendations for Stage 2 are included in Appendix 3.

#### Decisions by TAC/WSV

Based on the findings of Stage 1, TAC/WSV requested that for cervical epidural injections Stage 2 questions were to be addressed using the identified EBG. Due to the lack of synthesised evidence for lumbar epidural injections, the available RCT was used to address this intervention in Stage 2. Since no comparative studies were identified for thoracic epidural injections, no further action was required.

## Stage 2: Assessment of the interventions based on the best available evidence

### Appraisal

Synthesised research and primary studies were appraised using standard criteria by a single reviewer in consultation with colleagues as required. Details of the appraisals are in Appendix 4.

### Data extraction and synthesis

The most recent, comprehensive and high quality research for cervical and lumbar epidural injections was used to address the questions for Stage 2. Relevant data for outcomes of pain relief, function, return to work, adverse events and medicine and hospital utilisation were extracted. Findings reported in each of the evidence sources were compared and assessed for consistency.

## RESULTS

The database search yielded 13,124 citations for the combined review of epidural injections, facet joint injections and medial branch blocks. Removal of duplicates reduced this number to 8,758. After reviewing the title, abstract or full text, one systematic review, two RCTs and two cohort studies were found which met the selection criteria for epidural injections.

The internet search yielded an additional EBG. In total, one EBG, one systematic review, one RCT and two cohort studies were identified which met our selection criteria.

Many studies were excluded because they included comparators that did not meet our inclusion criteria, predominantly steroids and/or local anaesthetics.

The evidence identified included a variety of anatomical locations (eg. cervical or lumbar) with some considering more than one anatomical location. No evidence was identified that addressed thoracic epidural injections. The results are reported by anatomical location.

## 1. Cervical epidural injections

### 1.1 Identified evidence

Our search identified one EBG that addressed epidural injections for pain of cervical origin. This was published in 2007 and the literature search was conducted in 2005. One systematic review was identified, however this review could not be used for information about the effectiveness of epidural injections as studies using steroids and/or local anaesthetics as comparators were included. However the systematic review could be used for information about complications associated with epidural injections as the primary evidence underpinning their conclusions met our selection criteria. No HTAs were identified.

We also identified a cohort study whose aim was to assess complications of epidural injections for cervical radicular pain. No RCTs or CCTs were identified. The evidence identified is summarised in Table 1 below.

**Table 1. Identified evidence for cervical epidural injections**

| |
|---|
| **Evidence based guidelines** |
| New South Wales Government Motor Accident Authority (NSW MAA). Guidelines for the Management of Acute Whiplash-Associated Disorders for Health Professionals. NSW MAA, 2007; 2nd Edition. |
| **Health Technology Assessments** |
| None |
| **Systematic reviews** |
| Abdi S, Datta S, Trescot AM, Schultz DM, Adlaka R, Atluri SL, et al. Epidural steroids in the management of chronic spinal pain: a systematic review. Pain Physician 2007;10(1):185-212. |
| **Randomised controlled trials** |
| None |
| **Controlled trials** |
| None |
| **Cohort studies** |
| Huston CW, Slipman CW, Garvin C. Complications and side effects of cervical and lumbosacral selective nerve root injections. Archives of Physical Medicine & Rehabilitation 2005;86(2):277-83. |

The most comprehensive, rigorous and up-to-date source of synthesised evidence addressing effectiveness of epidural injections for pain of cervical origin is an EBG by the New South Wales Motor Accident Authority (NSW MAA) [3]. This EBG involved a systematic search of Medline, CINAHL, EMBASE, PEDro, HealthSTAR, PsycINFO, SportDiscus, the Cochrane Register of Clinical Trials, and bibliographies of retrieved articles from January 1999 to November 2005. A summary of the appraisal of the NSW MAA guideline can be found in Appendix 4.

Previously, we have considered synthesised evidence as 'current' when the search has been conducted within the previous two years. The search in the NSW MAA was conducted in November 2005, therefore would not be considered current. Usual practice would be to update this EBG by conducting a systematic review of the literature published since 2005. Our search did not identify any additional research published subsequent to this, so the NSW MAA EBG was considered to be the best available summary of the evidence in this area.

The most comprehensive, rigorous and up-to-date source of synthesised evidence addressing complications of epidural injections for pain of cervical origin is a systematic review by Abdi et al [4]. This systematic review involved a search of PubMed, EMBASE, and ISI Web of Science from January 1966 to October 2006; and a search of systematic reviews, narrative reviews, cross-references to the reviews, various published trials, and peer-reviewed abstracts from scientific meetings during the previous 2 years. A summary of the appraisal of the Abdi et al systematic review can be found in Appendix 4.

## 1.2 Quality of evidence

The EBG by NSW MAA and the systematic review by Abdi et al were well conducted and considered to have a low risk of bias.

## 1.3 Level of evidence

NSW MAA was unable to identify any evidence above level IV (based on NHMRC criteria) [5]. We were unable to find any evidence above level III-2. Therefore there is no evidence about effectiveness of cervical epidural injections above level III-2 to answer the Stage 2 questions posed by TAC/WSV.

The systematic review by Abdi contained level II and lower evidence, however only one cohort study (level III-2) met our inclusion criteria. In the systematic review, the findings about complications are presented for each study and therefore we are able to use only the information from the cohort study that meets our inclusion criteria, to answer the Stage 2 questions posed by TAC/WSV.

## 1.4 Scope

NSW MAA aimed to address interventions for managing acute and subacute neck pain following whiplash injury.

The systematic review by Abdi et al aimed to evaluate the effect of various types of epidural steroid injections (interlaminar, transforaminal, and caudal) in managing both axial and radicular chronic spinal pain in the neck and low back regions.

### *Age of patients*

The NSW MAA EBG included studies with participants aged from 18 years. Participant age was not addressed by Abdi et al.

### *Outcomes measured*

The outcomes specified in the NSW MAA EBG selection criteria included pain, disability, well-being/health related quality of life, employment status or return to work, cervical spine range of movement, medication use and adverse events.

Abdi et al specified pain relief at various points in time as the primary outcome measure. The secondary outcome measures were functional or psychological improvement, return to work, and complications. However due to reasons outlined above, only information about complications could be used in this review.

## 1.5 Findings

NSW MAA was unable to identify any evidence to address the Stage 2 questions posed by TAC/WSV. The systematic review by Abdi et al only provides information to address the question about risks.

### *In what conditions is this intervention indicated?*

Synthesised evidence can only answer this question if the studies identified have addressed it directly or if existing EBGs make specific recommendations. A review of the literature can only provide information about the patient groups and conditions in which the intervention has been applied in the studies available, and not whether this is appropriate or comprehensive. An additional level of expert clinical input is required to adapt this information into recommendations regarding indications for use.

The selection criteria for the NSW MAA included adult (>18 years) patients with an acute or subacute (<12 weeks) whiplash-associated disorder.

In the absence of evidence, the NSW MAA made a consensus recommendation that epidural steroid injections should not be used for patients with whiplash-associated disorders (WAD) Grades I or II. The EBG also recommended that occasionally, patients with WAD Grade III who have unresolved radicular pain that has persisted for more than one month might benefit from epidural steroid injections.

The selection criteria for Abdi et al included patients suffering with chronic spinal pain for at least three months.

### *What is the effectiveness of this intervention on pain in these conditions?*

NSW MAA was unable to identify any evidence to address this question.

### *What is the effect of this intervention on function, quality of life, return to work, medication use and healthcare utilisation?*

NSW MAA was unable to identify any evidence to address this question.

### *In what patient groups/conditions is this intervention contraindicated?*

The NSW MAA makes a consensus recommendation that epidural steroid injections should not be used for patients with whiplash-associated disorders classified as grade I or II.

### *What are the risks associated with use of this intervention?*

This was not addressed in the NSW MAA EBG.

Abdi et al included many studies, however only one of these met our inclusion criteria. From this study, Abdi et al noted that there were no major complications and that of the 9% who encountered side effects the most common was increased pain at the injection site. Abdi et al concluded that all types (interlaminal, transforaminal, and caudal) of epidural injections can be associated with complications and adverse events and attention to detail and caution should be practiced in order to improve safety and minimise complications.

## 1.6 Consistency of findings

Our search only identified one EBG addressing effectiveness therefore we are unable to make any comparisons. In addition to the systematic review by Aldi et al, a cohort study addressing complications was also identified. This study was included in the systematic review and is consistent with the review findings.

# 2. Thoracic epidural injections

We did not identify any relevant studies that evaluated the effectiveness of thoracic epidural injections.

# 3. Lumbar epidural injections

## 3.1 Identified evidence

Our search identified one systematic review [4] that addressed epidural injections for pain of lumbar origin, however as noted above this review could only be used for information about complications associated with epidural injections and not for information about effectiveness. The publication date of this systematic review was 2007 and the literature search was conducted in 2006. No EBGs or HTAs were identified.

We identified one RCT [6 7] and two cohort studies [2 8] assessing the effectiveness, cost-effectiveness and complications of epidural injections for pain of lumbar origin. No CCTs were identified.

The evidence identified is summarised in Table 2.

**Table 2. Identified evidence for lumbar epidural injections**

| **Evidence based guidelines** |
|---|
| None |
| **Health Technology Assessments** |
| None |
| **Systematic reviews** |
| Abdi S, Datta S, Trescot AM, Schultz DM, Adlaka R, Atluri SL, et al. Epidural steroids in the management of chronic spinal pain: a systematic review. Pain Physician 2007;10(1):185-212. |
| **Randomised controlled trials** |
| Karppinen J, Malmivaara A, Kurunlahti M, Kyllonen E, Pienimaki T, Nieminen P, et al. Periradicular infiltration for sciatica: a randomized controlled trial. Spine 2001; 26(9): 1059-67.<br>*Subgroup analysis for cost effectiveness in additional publication:*<br>Karppinen J, Ohinmaa A, Malmivaara A, Kurunlahti M, Kyllonen E, Pienimaki T, et al. Cost effectiveness of periradicular infiltration for sciatica: subgroup analysis of a randomized controlled trial. Spine 2001;26(23):2587-95. |
| **Controlled trials** |
| None |
| **Cohort studies*** |
| Huston CW, Slipman CW, Garvin C. Complications and side effects of cervical and lumbosacral selective nerve root injections. Archives of Physical Medicine & Rehabilitation 2005;86(2):277-83. |
| Manchikanti L, Pampati V, Rivera JJ, Beyer C, Damron KS, Barnhill RC. Caudal epidural injections with Sarapin or steroids in chronic low back pain. Pain Physician 2001;4(4):322-335. |

*Primary studies are ordered by publication date.

No synthesised evidence regarding the effectiveness of epidural injections in pain of lumbar origin was identified, therefore the one available RCT has been appraised and used to address the Stage 2 questions posed by TAC/WSV. A summary of the appraisal of Karppinen et al can be found in Appendix 4.

The most comprehensive, rigorous and up-to-date source of synthesised evidence addressing complications of epidural injections for pain of cervical origin is the systematic review by Abdi et al [4]. This systematic review involved a search of PubMed, EMBASE, and ISI Web of Science from January 1966–October 2006; and a search of systematic reviews, narrative reviews, cross-references to the reviews, various published trials, and peer-reviewed abstracts from scientific meetings during the previous 2 years. A summary of the appraisal of the Abdi et al systematic review can be found in Appendix 4.

## 3.2 Quality of evidence

The RCT by Karppinen et al and the systematic review by Abdi et al were well conducted and considered to have a low risk of bias.

## 3.3 Level of evidence

The RCT addressing effectiveness provides level II evidence.

The systematic review contained level II and lower evidence, however only one cohort study (level III-2) met our inclusion criteria. In the systematic review, the findings about complications are presented for each study and therefore we are able to use the information from the single cohort study that meets our inclusion criteria to answer the Stage 2 questions posed by TAC/WSV.

## 3.4 Scope

The RCT by Karppinen et al tested the efficacy of fluoroscopically guided periradicular epidural injections of steroid plus local anaesthetic compared to saline for the treatment of sciatica in adults.

The systematic review by Abdi et al aimed to evaluate the effect and associated complications of various types of epidural steroid injections (interlaminar, transforaminal, and caudal) in managing both axial and

radicular chronic spinal pain in the neck and low back regions. However due to reasons outlined above, only information about complications could be used in this review.

### *Outcomes measured*

Outcomes measured by Karppinen et al included back and leg pain, function, quality of life, return to work, and cost of medication use and health care utilisation.

Abdi et al specified pain relief at various points in time as the primary outcome measure. The secondary outcome measures were functional or psychological improvement, return to work, and complications.

## 3.5 Findings

### *In what conditions is this intervention indicated?*

A literature review can only answer this question if the studies identified have addressed it directly or if existing EBGs make specific recommendations. A review of the literature can only provide information about the patient groups and conditions in which the intervention has been applied in the studies available, and not whether this is appropriate or comprehensive. An additional level of expert clinical input is required to adapt this information into recommendations regarding indications for use.

We were unable to identify any specific indications for use. Karppinen et al used this intervention in adult patients with unilateral symptoms of sciatica of one to six months duration and in Abdi et al the selection criteria included patients suffering with chronic spinal pain for at least three months.

### *What is the effectiveness of this intervention on pain in these conditions?*

Karppinen et al found that leg pain was significantly better following epidural injections of steroid plus local anaesthetic immediately after the intervention and at two weeks follow-up compared to the saline group. At three months there was no difference in leg pain between treatment and control groups but at six months follow-up, leg pain was worse in the treatment group compared to those in the control group.

There was no difference between treatment and control groups in back pain immediately after the intervention and at two weeks follow-up. Back pain was better following saline at three and six months follow up.

No difference was found between the treatment and control groups in leg or back pain by one year.

Based on these findings, the evidence of effectiveness for lumbar epidural injections is inconclusive.

### *What is the effect of this intervention on function, quality of life, return to work, medication use and healthcare utilisation?*

Karppinen et al found that patients who received steroid plus local anaesthetic had better straight leg raising and lumbar flexion than those that received saline two weeks after injection, but found no difference between the two groups at one year. Patient satisfaction, sick leave and costs for medication and healthcare utilisation were similar between groups at one year. Medication use and healthcare utilisation were not addressed.

### *In what patient groups/conditions is this intervention contraindicated?*

This is similar to the question regarding indications for use. A literature review can only answer this if the studies identified have addressed it directly or if existing guidelines make specific recommendations. Some information from a review of the literature may be relevant in this context, such as the patient groups and conditions excluded from the available studies or any adverse outcomes that may have occurred in specific patient groups, but cannot be translated directly into contraindications. An additional level of expert clinical input is required to adapt this information into recommendations regarding patient groups or conditions that are contraindicated for use.

The authors of the RCT did not specify any patient groups/conditions for which this intervention is contraindicated.

### *What are the risks associated with use of this intervention?*

This was not addressed in the RCT by Karppinen et al. Abdi et al included many studies, however only one of these met our inclusion criteria. From this study, Abdi et al noted that there were no major complications and that of the 9% who encountered side effects the most common was increased pain at the injection site. Abdi et al concluded that all types (interlaminal, transforaminal, and caudal) of epidural injections can be

associated with complications and adverse events and that attention to detail and caution should be practiced in order to improve safety and minimise complications.

### 3.6 Consistency of findings

In addition to the RCT by Karppinnen et al, a cohort study addressing effectiveness was also identified. Manchikanti et al [8] reported that epidural injections of steroid plus local anaesthetic are an effective modality of treatment in managing chronic, persistent low back pain that fails to respond to conservative modalities of treatments. Cost data was also reported and the authors concluded that epidural injections were cost effective.

There is inconsistency in findings, both within the RCT and between the RCT and the cohort study, in terms of clinical effectiveness and cost effectiveness.

An additional cohort study addressing complications and side effects of lumbar epidural injections was also identified. Huston et al [2] was included in the systematic review by Abdi et al the findings are consistent.

## DISCUSSION

As there were a number of published EBGs and systematic reviews available, a pragmatic yet rigorous approach to identify the best available source of synthesised evidence for epidural injections was undertaken to address the questions outlined in Stage 2.

Use of EBGs and systematic reviews to address specific clinical questions is limited by the intended purpose of the synthesised evidence and the way the authors report findings from primary evidence. Findings can only be reported for clinical questions that have been addressed by an individual EBG or systematic review and can only be described to the level of detail provided in the synthesised evidence. This approach also means we are unable to conduct our own critical appraisal of primary studies and must rely on the methodology of the review authors to comment on the validity and reliability of results.

Although there was a huge body of literature identified by our search, there were very few relevant reports of synthesised research and comparative studies which evaluated the effectiveness of epidural injections for patients with acute or chronic neck or back pain. One EBG was identified for cervical epidural injections and one RCT and one cohort study were identified for lumbar epidural injections with steroid plus local anaesthetic. A systematic review and a cohort study addressing complications of cervical and lumbar epidural injections were identified. No evidence was identified for thoracic epidural injections.

Since steroids and local anaesthetics were used as interventions in this review, studies that included either of these as comparators were excluded. Studies that did not use fluoroscopic guidance to administer epidural injections were also excluded. Many of the studies initially identified were excluded based on these two criteria, significantly reducing the number available to address the questions of this review.

While there was one EBG that met our selection criteria addressing the effectiveness of cervical epidural injections, it was unable to identify any evidence and therefore made a consensus recommendation that epidural steroid injections should not be used for patients with whiplash-associated disorders (WAD) Grades I or II. This review considered patients with acute or subacute pain present for less than 12 weeks.

The results of studies addressing lumbar epidural injections indicate that there may be benefit in the short term (up to three months) for back pain and function, but leg pain was worse in the treatment group. No differences were found at 12 month follow up. This study enrolled patients with chronic pain present from six to 28 weeks.

We noted that there were a number of approaches when administering epidural injections (interlaminal, transforaminal, and caudal), however there was insufficient evidence to decide whether one approach was better than another.

## Limitations of this review

Limitations of our review are that only studies in English were included and hand-searching was not undertaken. The implication of this is that some relevant studies may have been missed. In addition, the application of selection criteria, appraisal of studies and extraction of the data was conducted by only one person. This may have lead potentially to errors or bias.

## CONCLUSION

Information is only available for cervical and lumbar epidural injections.

There is insufficient evidence available to provide any information on the effectiveness of cervical epidural injections.

No relevant studies were identified which assessed the effectiveness of thoracic epidural injections for pain. Therefore we conclude that there is no evidence of effectiveness of this intervention.

The available evidence of effectiveness for lumbar epidural injections is inconclusive.

There is insufficient evidence available to provide specific information about the risks of epidural injections, however authors advise that attention to detail and caution should be practiced in order to improve safety and minimise complications.

## DISCLAIMER

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The TAC/WSV Health Services Group has engaged CCE and ACC for their objectivity and independence and recognises that any materials developed must be free of influence from parties with vested interests. The Evidence Service has full editorial control.

## REFERENCES


1. Price C, Arden N, Coglan L, Rogers P. Cost-effectiveness and safety of epidural steroids in the management of sciatica. *Health Technology Assessment* 2005;9(33):iii, ix-x, 1-58.
2. Huston CW, Slipman CW, Garvin C. Complications and side effects of cervical and lumbosacral selective nerve root injections. *Archives of Physical Medicine & Rehabilitation* 2005;86(2):277-83.
3. NSWMAA. Guidelines for the Management of Acute Whiplash-Associated Disorders for Health Professionals New South Wales Government Motor Accident Authority 2007;2nd Edition.
4. Abdi S, Datta S, Trescot AM, Schultz DM, Adlaka R, Atluri SL, et al. Epidural steroids in the management of chronic spinal pain: a systematic review. *Pain Physician* 2007;10(1):185-212.
5. National Health and Medical Research Council, How to use the evidence: assessment and application of scientific evidence 2000: Commonwealth of Australia.
6. Karppinen J, Malmivaara A, Kurunlahti M, Kyllonen E, Pienimaki T, Nieminen P, et al. Periradicular infiltration for sciatica: a randomized controlled trial.[see comment]. *Spine* 2001;26(9):1059-67.
7. Karppinen J, Ohinmaa A, Malmivaara A, Kurunlahti M, Kyllonen E, Pienimaki T, et al. Cost effectiveness of periradicular infiltration for sciatica: subgroup analysis of a randomized controlled trial. *Spine* 2001;26(23):2587-95.
8. Manchikanti L, Pampati V, Rivera JJ, Beyer C, Damron KS, Barnhill RC. Caudal epidural injections with Sarapin or steroids in chronic low back pain. *Pain Physician* 2001;4(4):322-335.
9. The Cochrane Collaboration (2006) Commercial sponsorship and The Cochrane Collaboration. April 2006 [Access Date]; Available from: http://www.cochrane.org/docs/commercialsponsorship.htm.
10. The AGREE Collaboration. Appraisal of Guidelines for Research & Evaluation (AGREE) Instrument .

# APPENDIX 1: TWO-STAGE REVIEW PROCESS

## Review of Epidural Injections

The scoping exercise identified a variety of evidence resources. Some high level studies (EBGs, systematic reviews, RCTs) were available for this intervention. In light of this we propose a two-staged approach.

## Process

## Stage 1

### Identify evidence available for each intervention

- Write search, limit to evidence-based guidelines, HTAs, systematic reviews, RCTs, CCTs and cohort studies
- Run search in health databases, websites and on the internet
- Apply inclusion and exclusion criteria

### Critically appraise synthesised research

- Start with most recent review, apply standard appraisal criteria
  - If found to be of high quality, cross check to ensure references from all other synthesised research are included and check for consistency of findings
  - If not high quality, appraise next most recent, and repeat process
- If there are inconsistent findings across the existing reviews, investigate the possibility of synthesis of this information or whether a new systematic review is required

### Identify need for additional systematic reviews

- Map available evidence (as per TableA1. 1)
- Identify whether sufficient high level evidence exists to address Stage 2 or indicate whether synthesis of available evidence is required (based on algorithm in Table A1.2) eg.
  - Updating good quality but out-of-date systematic review
  - Conducting new systematic review where no good quality systematic review found

### Seek direction from TAC/WSV

## Stage 2

Based on directions from TAC/WSV, address questions regarding indications, efficacy, outcomes, contraindications and risks using one of the following approaches

- Use existing high level evidence (EBGs, systematic reviews or HTAs) identified in Stage 1
- Update existing high quality systematic review
- Conduct new systematic review

**Table A1.1. Map of available evidence addressing epidural injections**

| Anatomical Location | Evidence-Based Guidelines | Systematic Reviews/HTAs | Primary studies | Conditions assessed |
|---|---|---|---|---|
| Cervical | | | | |
| Thoracic | | | | |
| Lumbar | | | | |

**Table A1.2. Further action required to answer clinical questions**

<table>
<tr><td colspan="4">Is there any synthesised research available? (eg. EBGs, HTAs, systematic reviews, RCTs)</td></tr>
<tr><td colspan="3">Yes</td><td>No</td></tr>
<tr><td colspan="3">Is this good quality research?</td><td>Are RCTs available?</td></tr>
<tr><td colspan="2">Yes</td><td>No</td><td>Yes</td><td>No</td></tr>
<tr><td colspan="2">Is it current (within 2 years)?</td><td rowspan="2"></td><td rowspan="2"></td><td rowspan="2">Consider looking for lower levels of evidence</td></tr>
<tr><td>Yes</td><td>No</td></tr>
<tr><td>No further action</td><td>Update existing SR</td><td>Undertake new SR</td><td>Undertake new SR</td><td></td></tr>
</table>

**Note re safety of technologies or clinical practices**

The details above are based on finding existing synthesised information or conducting systematic reviews of RCTs. This will provide the best information regarding effectiveness of the technology or clinical practice in question.

However this method may not identify all potential safety issues. The sample size for an RCT is calculated based on the likelihood of finding a clinically important outcome. This process may not identify rare adverse events, or adverse events that occur beyond the follow up period of the study. More complex searches that include cohort studies, case-control studies and case series may be required to give a complete picture of adverse events that may not have been identified through RCTs. These searches require additional time and resources.

## APPENDIX 2: METHODS

This review was addressed according to a two-stage process as outlined in Appendix 1. Methods used to address Stage 1 are described below.

TAC/WSV staff assisted in the development of search terms and inclusion and exclusion criteria.

## Selection criteria

Inclusion and exclusion criteria were established *a priori* (Table A2.1) and were applied by a single reviewer.

**Table A2.1. Selection criteria**

| | |
|---|---|
| **Patient/ population** | **Inclusion:** Patients with neck, back, sacroiliac joint or radicular pain (including sciatica, brachialgia and cervicobrachialgia) following trauma (including occupational injury eg. prolonged sitting); arthritis resulting from trauma; degenerative disc disease. |
| | **Exclusion:** Non-traumatic pain eg. cancer pain, trigeminal neuralgia, spondyloarthropathies; pain associated with childbirth; acute post-operative pain (eg. abdominal surgery, hip or knee replacement, thoracotomy). |
| **Intervention/ indicator** | The review included interventions administered at any stage of the management of pain eg. first-line, second-line, when all else fails, as an adjunct to therapy. |
| | **Inclusion:** Radiologically guided (including fluoroscopy, CT, MRI and ultrasound) epidural injection of steroid (particulate or non-particulate) and/or local anaesthetic. Epidural injection (caudal, interlaminar, transforaminal), also called:<br>• spinal nerve root sleeve injection<br>• spinal nerve root injection<br>• spinal nerve root block<br>• periradicular infiltration<br>• perineural injection<br>• dorsal root ganglion nerve injection<br>• dorsal root ganglion injection<br>• dorsal root ganglion block |
| | **Exclusion:** Non-radiologically guided injection; injection of substances other than steroids and/or local anaesthetic; continuous delivery of epidural infusion; injection given via a catheter; intrathecal injections/infusions; greater and lesser occipital nerve block; sympathetic ganglion injection. |
| **Comparison/ control** | **Inclusion:** Placebo procedure (eg. injection of saline), sham procedure (eg. injection of saline into an alternative site, where saline is not known to be active therapy for that site), usual care (eg. medical consultations, analgesics, exercise, physiotherapy, chiropractic, osteopathy, surgery (eg. microdiscectomy and laminectomy). |
| | **Exclusion:** Steroid and/or local anaesthetic and all other interventions that are not listed in the inclusion criteria. |
| **Outcomes** | **Inclusion:** Pain, function, return to work, quality of life, medication use, harmful effects or adverse events. |
| | **Exclusion:** Nil |
| **Setting** | **Inclusion**: Any healthcare setting (eg. acute, subacute, rehabilitation, community). |
| | **Exclusion:** Nil |
| **Study Design** | **Inclusion:** EBGs, systematic reviews, HTAs, RCTs, CCTs, cohort studies. |
| | **Exclusion:** Non-evidence-based guidelines, non-systematic reviews, case-control studies, case series, editorials, letters, commentaries, earlier superseded versions of EBGs or systematic reviews. |
| **Publication details** | **Inclusion:** Studies in English and conducted on humans. |
| | **Exclusion:** Studies in languages other than English and/or conducted on animals. |
| **Time period** | **Inclusion:** Any publication date. |
| | **Exclusion:** Nil |

## Search strategy

A systematic review for facet joint injections and medial branch blocks was conducted concurrently. As there was found to be a substantial overlap between the two reports, the database and internet searches were undertaken together and application of inclusion and exclusion criteria was conducted on the combined dataset by one reviewer in consultation with colleagues as required.

Based on the agreed methodology in the two-stage proposal, searches were limited to EBGs, systematic reviews, HTAs, RCTs, CCTs and cohort studies.

Standard systematic review strategies, as outlined below, were used to identify existing reviews and trials. Additional strategies were included to identify EBGs.

## Electronic databases

**Table A2.2. Databases accessed**

| Evidence Source | Period | Date of Search |
|---|---|---|
| Medline (Ovid) | 1950 to present | 22nd December 2008 |
| All EBM (Ovid) * | | 22nd December 2008 |
| CINAHL (Ovid) | 1982 to December Week 2 2008 | 22nd December 2008 |
| EMBASE | 1980 to 2008 Week 51 | 22nd December 2008 |

* including The Cochrane Database of Systematic Reviews (4th Quarter 2008); ACP Journal Club (1991 to November 2008); DARE, CENTRAL, CMR, HTA and NHSEED (4th Quarter 2008)

### *Database search*

The following search was conducted in Medline and adapted for use in other databases.

No terms have been included for comparison or outcomes to enable a broader search.

**Table A2.3. Database search**

| | | | |
|---|---|---|---|
| 1 | exp Pain/ | 21 | epidural.mp. |
| 2 | pain.mp. | 22 | spinal.mp. |
| 3 | 1 or 2 | 23 | spine.mp. |
| 4 | exp Back/ | 24 | dorsal root ganglion.mp. |
| 5 | back.mp. | 25 | perineural.mp. |
| 6 | Neck/ | 26 | or/21-25 |
| 7 | neck.mp. | 27 | inject$.mp. |
| 8 | spinal.mp. | 28 | Injections/ |
| 9 | spine.mp. | 29 | block$.mp. |
| 10 | radicular.mp. | 30 | 27 or 28 or 29 |
| 11 | or/4-10 | 31 | 26 and 30 |
| 12 | 3 and 11 | 32 | Injections, Spinal/ |
| 13 | Radiculopathy/ | 33 | Injections, Epidural/ |
| 14 | radiculopath$.mp. | 34 | nerve block/ |
| 15 | Sciatica/ | 35 | nerve block$.mp. |
| 16 | Sciatica.mp. | 36 | neural block$.mp. |
| 17 | cervicobrachialgia.mp. | 37 | periradicular infiltration.mp. |
| 18 | cervico-brachialgia.mp. | 38 | or/31-37 |
| 19 | brachialgia.mp. | 39 | 20 and 38 |
| 20 | or/12-19 | 40 | limit 39 to (english language and humans) |

## Guideline searches

EBGs are generally published as electronic ‘stand alone’ documents on the internet rather than papers in peer reviewed journals. The search to identify EBGs is therefore quite different to searches usually

undertaken for systematic reviews of primary research in the health literature. Methods to identify EBGs include identification of relevant websites followed by searches within them, direct searches of the internet and searches within the electronic health databases.

Unlike systematic reviews of the primary research literature which usually involve a single clinical question, an EBG is a compilation of systematic reviews arising from numerous clinical questions. These reviews may be grouped within the EBG into sections or chapters based on patient characteristics, health care settings, domains of clinical care or other categories related to the particular condition or patient population. Due to this complexity and comprehensiveness, the information contained in a particular section or chapter may be found in more than one type of EBG.

### *Website searches to identify relevant evidence-based guidelines*

The reviewers were aware of websites of guideline clearinghouses, guideline developers, centres of evidence-based practice, Australian government health services and websites of specific relevance (eg. accident compensation groups) known to contain evidence-based resources.

The 25 websites previously identified by the review team (13 professional organisations, 9 guideline services, 2 Australian government websites and 1 centre of evidence-based practice) were searched for relevant EBGs. Details of websites searched can be found in Table A2.4.

Where an internal search engine was available, websites were searched using the following search strings.

- (epidural OR facet joint) AND (injection)
- (med* OR nerve OR branch OR dorsal OR posterior) AND (block) AND (pain)

If no search engine was available, lists of EBGs, publications or other resources identified on the site were scanned for relevant documents.

The searches are outlined in detail in Table A2.4.

### *Internet searches to identify relevant evidence-based guidelines and systematic reviews*

An internet search strategy was conducted using the Google 'Advanced Search' function. The search string was limited to documents in English:

(spinal OR epidural OR facet OR sacro OR nerve OR intraarticular OR zygapophys OR ramus OR root OR perineural OR branch) AND (injection OR block) AND (evidence OR guideline OR systematic)

The searches are outlined in detail in Table A2.5.

**Table A2.4. Website searches to identify relevant guidelines (searched for epidural injections, medial branch blocks, facet joint injections and sacroiliac joint injections)**

| **Guideline Services** | | |
|---|---|---|
| National Health and Medical Research Council (NHMRC) | www.nhmrc.gov.au | Web page reviewed: Guidelines, health |
| National Institute for Health and Clinical Excellence UK (NICE) | www.nice.org.uk | Web page reviewed: Our guidance, health topic, injury, accident & wounds<br>Web page reviewed: Our guidance, health topic, musculoskeletal<br>Web page reviewed: Our guidance, health topic, surgical procedures, bones and joint surgery<br>Web page reviewed: Our guidance, health topic, surgical procedures, nervous system surgery |
| New Zealand Guideline Group (NZGG) | www.nzgg.org.nz | Web page reviewed: Guidelines and Reports<br>Additional search by: evidence for practice, primary care guidelines |
| Scottish Intercollegiate Guidelines Network (SIGN) | www.sign.ac.uk | Web page reviewed: Guidelines |
| Joanna Briggs Institute | www.joannabriggs.edu.au | Web page reviewed: Systematic reviews & best practice information (member access only) |
| Guidelines International Network | www.g-i-n.net | Web page reviewed:: International Guideline Library (members only)<br>Searched by keywords: spinal, injection, block |
| Guidelines Advisory Committee | www.gacguidelines.ca | Web page reviewed: List all topics and summaries |
| National Guideline Clearinghouse US (NGC)<br>(1) **searched on 09/02/09 – 47 Results total**<br>(2) **searched on 09/02/09 – 92 Results total** | www.guidelines.gov | Searched by:<br>(1) ((epidural OR facet joint) AND injection)<br>(2) (((med* OR nerve OR branch OR dorsal OR posterior) AND block) AND pain) |
| TRIP Database<br>(1) **searched on 09/02/09 – 159 Results total**<br>(48 – North America, 37 – Europe, 9 – Other) + 65 systematic reviews | www.tripdatabase.com | Searched by:<br>(((epidural OR facet joint) AND injection) OR ((medial OR nerve OR branch OR dorsal OR posterior) AND block) AND pain) – limited by guidelines and systematic reviews |
| **Australian Government Websites containing Guidelines** | | |
| Australian Government Department of Health and Ageing | www.health.gov.au | Web page reviewed: Health Professionals – Treatments & Techniques – Guidelines |
| NSW Health | www.health.nsw.gov.au | Web page reviewed: Publications & Resources – Policy Directives and Guidelines |
| **Centres of Evidence Based Practice Websites** | | |
| WA Centre for Evidence Based Nursing and Midwifery | http://wacebnm.curtin.edu.au | Web page reviewed: Resources – 'Reports, Guidelines and Article' |
| **Other Accident Commissions** | | |
| Motor Accidents Authority NSW | www.maa.nsw.gov.au/ | Web page reviewed: Publications & Reports – MAA Guidelines – Guides for Professionals |

| | | |
|---|---|---|
| Accident Compensation Corporation | www.acc.co.nz/index.htm | Web page reviewed:: For Providers – Guidelines & Best Practice – Published Clinical Guidelines |
| Pain Treatment Topics | http://pain-topics.org/guidelines_reports/index.php | Web page reviewed: Current Pain Treatment Guidelines |
| WorkSafe VIC | www.workcover.vic.gov.au | Web page reviewed: Safety & Prevention; Health and Safety Topics |
| Work Cover NSW | www.workcover.nsw.gov.au | Web page reviewed: Publications |
| Work Cover WA | www.workcover.wa.gov.au | Web page reviewed: Publications – Publications for health providers |
| **Pain Websites** | | |
| British Pain Society | http://www.britishpainsociety.org | Web page reviewed: Publications |
| Faculty of Pain Medicine – Australian New Zealand College of Anaesthetists | http://www.anzca.edu.au/fpm/ | Web page reviewed:: Resources, Professional Documents |
| American Pain Society | http://www.ampainsoc.org | Web page reviewed: Publications, Clinical Practice Guidelines |
| The American Academy of Pain Medicine | http://www.painmed.org/ | Web page reviewed: Clinical Information, Clinical Guidelines |
| The Pain Association of Singapore | http://www.pain.org.sg/ | Web page reviewed: Pain Guidelines and Management |

**Table A2.5. Internet searches to identify relevant guidelines and systematic reviews**

| **Search 2: Identification of relevant guidelines for epidural steroid injections, facet joint injections, sacroiliac joint injections and medial branch blocks using Google** | |
|---|---|
| Find web pages that have **all these words** | eg. (spinal OR epidural OR facet OR sacro OR nerve OR intraarticular OR zygapophys OR ramus OR root OR perineural OR branch) AND (injection OR block) AND (evidence OR guideline OR systematic) |
| Find web pages that have this **exact wording or phrase** | |
| Find web pages that have **one or more of these words** | |
| **Don't** show pages that have **any of these unwanted words** | |
| **Language** | English |
| **Results (12/02/09) completed search:** | 47,400,000 |
| Google Edits at | 545 |

### *Citation searches*

Reference lists of potentially relevant publications were searched to identify any further primary or secondary studies. Any relevant primary studies identified in our search were used in a citation search in the Web of Science database to identify any further studies that met our inclusion criteria.

## Appraisal

Appraisal was undertaken in steps.

1. The most recent review (EBG, systematic review or HTA) was assessed for quality using standard appraisal criteria.
2. If found to be of high quality, it was cross checked against the other available reviews to compare scope and consistency of findings.
3. If found not to be of high quality, the next most recent was appraised and the above process repeated.

## Quality

### *Evidence-based guidelines and systematic reviews*

The synthesised evidence was appraised using standard criteria by a single reviewer in consultation with colleagues as required. Usually EBGs are appraised using the AGREE criteria [10], however this instrument has some limitations, particularly in relation to appraisal of the systematic review methods used by the EBG developers.

### *Other study designs*

Where EBGs or systematic reviews were not identified, critical appraisal of other study designs was to be limited to high level trials identified in our search that had not been previously described in the synthesised literature. Other study designs were appraised using standard criteria by a single reviewer in consultation with colleagues as required.

Details of quality appraisals are included in Appendix 4.

## Level of evidence

Levels of evidence reflect the methodological rigour of studies. We used the National Health and Medical Research Council (NHMRC) [5] levels of evidence classification system . A study assigned as level I evidence is considered the most rigorous and least susceptible to bias, while a study deemed to be level IV evidence is considered the least rigorous and is more susceptible to bias. See Table A2.6 for details.

Studies found to be of poor methodological quality cannot be assigned a level of evidence.

**Table A2.6. Designation of levels of evidence**

| | |
|---|---|
| **Level I** | Evidence obtained from a systematic review of all relevant randomised controlled trials |
| **Level II** | Evidence obtained from at least one properly designed randomised controlled trial |
| **Level III-1** | Evidence obtained from well-designed pseudo-randomised controlled trials (alternate allocation or some other method) |
| **Level III-2** | Evidence obtained from comparative studies with concurrent controls and allocation not randomised (cohort studies), case-control studies or interrupted time series with a control group |
| **Level III-3** | Evidence obtained from comparative studies with historical control, two or more single-arm studies or interrupted time series without a parallel control group |
| **Level IV** | Evidence obtained from case series, either post-test or pre-test and post-test |

## Scope

Patient groups included and outcomes measured in the studies identified for each intervention were reviewed to consider the scope covered and identify any gaps in the information provided.

## Consistency of findings

The findings reported by separate studies were compared and assessed for consistency. In cases where findings appear to be inconsistent with other studies, these were further explored to determine whether differences in study design, scope, or quality can explain disparate findings between studies.

# APPENDIX 3. EVIDENCE MAP AND RECOMMENDATIONS

**Table A3.1. Evidence map**

| Intervention | EBGs | SRs/HTAs | RCTs | CTs | Cohort studies |
|---|---|---|---|---|---|
| Cervical epidural injections | 1 | 1 | 0 | 0 | 1 |
| Thoracic epidural injections | 0 | 0 | 0 | 0 | 0 |
| Lumbar epidural injections | 0 | 1 | 2 | 0 | 2 |

## 1. Cervical epidural injections

A rigorous and comprehensive guideline is available on this topic. It was published in 2007 but the search date is 2005. Our normal approach would be to say that we would update this review by searching forward from this search date. However our search did not identify any additional studies that address effectiveness of this intervention. We did find another systematic review but the only information within it that met our selection criteria was about complications of the procedure.

### Recommendations for further action

We recommend that no further evidence synthesis is required and that we use the information available to answer the TAC/WSV questions.

A second option would be to undertake a systematic review of low level studies. This will be very time consuming, particularly as there is a huge amount of literature on these topics, and will only provide observational studies. The inherent bias with this level of evidence will provide limited confidence in the information to answer the TAC/WSV questions.

## 2. Thoracic epidural injections

No synthesised evidence, RCTs, CCTs or cohort studies were found which were relevant to this intervention.

### Recommendations for further action

We recommend that no further evidence synthesis is undertaken and that the review reports that there is no evidence of effectiveness.

## 3. Lumbar epidural injections

No synthesised evidence was found regarding effectiveness, but the review on complications is also relevant here. There is one RCT and two cohort studies available.

### Recommendations for further action

We recommend that appraisal of the RCT (and possibly cohorts depending on the quality of the RCT) is undertaken and that we use this information to answer the TAC/WSV questions.

# APPENDIX 4. APPRAISAL OF STUDY QUALITY

**Table A4.1. Quality Appraisal of EBG Addressing Effectiveness of Cervical Epidural Injections**

**Study: NSW MAA (2007) Guidelines for the Management of Acute Whiplash-Associated Disorders for Health Professionals New South Wales Government Motor Accident Authority. 2nd Edition.**

| Description of study: Systematic review | |
|---|---|
| **Patient/population** | Adults with acute or subacute simple neck pain after a motor vehicle accident. |
| **N** | No studies identified for epidural injections. |
| **Setting** | First 12 weeks after a motor vehicle accident when a whiplash-associated disorder (WAD) is the only injury or when it has occurred concurrently with other injuries. |
| **Intervention/indicator** | Epidural steroid injections (among other interventions included in this EBG). |
| **Comparison/control** | Placebo, sham or no treatment. |
| **Outcomes** | Pain; disability; well-being/health related quality of life; employment status or return to work; cervical spine range of movement; medication use; and adverse events. |
| **Inclusion Criteria** | Participants: "Studies were only included if a criterion for entry was acute or subacute onset WAD (< 12 weeks duration) or in trials of mixed duration neck pain in which subjects with acute or subacute WAD were easily differentiated for analysis. Studies that evaluated individuals of age groups > 18 years of either sex were included. Studies were included if more than 50% of the evaluated subjects' primary complaint (as a result of a MVA) was neck pain or neck pain and headache, or neck pain and dizziness, or neck pain and arm pain. Studies evaluating WAD Grades I–IV were included. In addition, systematic reviews specifically investigating whiplash were included."<br><br>Studies: "RCTs and quasi-RCTs were included for appraisal. Quasi-RCTs allocate participants to study groups in ways that are intended to be random but are not strictly random (e.g., sequential attendance at a clinic). RCTs were included if they compared one intervention in patients with WAD against a control group (no treatment, placebo or sham treatment). Studies that compared treatment as a supplement to another therapy were also included. Any systematic review of RCTs investigating treatment of patients with acute or subacute (< 12 weeks duration) WAD published since 1999 was also included." |
| **Exclusion Criteria** | Studies in which the evaluated subjects' main complaint was headache, dizziness or arm pain only, without neck pain, were excluded. |

| Study Validity | | |
|---|---|---|
| **Were there any conflicts of interest in the writing or funding of this review?** | Not reported | |
| **Were reviewers blind to authors, institutions and affiliations?** | Not reported | |
| **Does the review have a clearly-focused question?** | Yes | |

| | | |
|---|---|---|
| **Does the review have specified inclusion/exclusion criteria?** | Yes | See above. Further detail can be found in Technical Report: Guidelines for the management of acute whiplash-associated disorders. |
| **Were 2 or more independent reviewers used for:**<br>**1. application of inclusion criteria to assess eligibility of studies?** | Yes | "The 4089 titles identified by the search strategy were screened independently by two assessors using the eligibility criteria outlined above. Any disagreement was resolved by mutual consent." |
| **2. extraction of data from study reports?** | Yes | "The results, study participants, treatment undertaken and dose used, comparison groups, and follow-up rates were independently extracted from each study." |
| **3. appraisal of study quality?** | Yes | "Two independent assessors were used to rate each study. A third assessor was consulted when contention existed." |
| **If there were specified inclusion/ exclusion criteria, were these appropriate??** | Yes | Described in detail in Technical Report: Guidelines for the management of acute whiplash-associated disorders. |
| **Does the review document a comprehensive search strategy?** | Yes | Described in detail in Technical Report: Guidelines for the management of acute whiplash-associated disorders - 6.4: Search strategies and Appendix 6: Treatment search strategies. |
| **Was the validity of included trials appraised using appropriate criteria?** | Yes | RCTs: "The 20 RCTs abstracts that met the eligibility criteria were assessed fully for inclusion criteria and for methodological quality using the PEDro scale (8). It was decided to use this scale because it contains items related to internal, external and statistical validity, which were all deemed important for the conduct of the review."<br>Systematic reviews: "The abstracts of the 23 systematic reviews that met the inclusion criteria were then fully screened for eligibility and, where appropriate, scored for quality using a modified QUOROM standards checklist (Table 6.2). This modified checklist included items concerning the conduction of the review, reporting of results, and discussion of results, which were deemed important for the current review." |
| **Is there a summary of the results of individual studies?** | Yes | Evidence tables provided in Technical Report: Guidelines for the management of acute whiplash-associated disorders. |
| **Were the strengths and limitations of included studies and potential impact on the results discussed?** | Yes | In the evidence tables provided in Technical Report: Guidelines for the management of acute whiplash-associated disorders. |
| **If meta-analyses were conducted, was it reasonable to do so?** | Not applicable | |
| **If meta-analyses were conducted, was it done appropriately?** | Not applicable | |
| **Other** | | |

| | | |
|---|---|---|
| **What is the overall risk of bias?** | Low | *Most of the criteria have been fulfilled or where criteria have not been fulfilled it is very unlikely the conclusions of the review would be affected.* |

## Results

"No level I or II evidence." The NHMRC levels of evidence have been used.

## Author's Conclusions

"Epidural steroid injections should not be used for patients with WAD Grades I or II. Occasionally, patients with WAD Grade III who have unresolved radicular pain that has persisted for more than one month might benefit from epidural steroid injections."

## Our comments/summary

This EBG contains a well conducted systematic review of the evidence to underpin the recommendations. No level I or II evidence was identified to make a recommendation about epidural steroid injections, however in the previous edition of the EBG, the above consensus recommendation was made and this recommendation was carried forward into the updated EBG in the continued absence of evidence.

**Table A4.2. Quality Appraisal of RCT Addressing Effectiveness of Lumbar Epidural Injections**

**Study:**

1. **Karppinen, J., A. Malmivaara, M. Kurunlahti, E. Kyllonen, T. Pienimaki, P. Nieminen, A. Ohinmaa, O. Tervonen and H. Vanharanta (2001) Periradicular infiltration for sciatica: a randomized controlled trial. Spine. 26(9): p. 1059-67.**
2. **Karppinen, J., A. Ohinmaa, A. Malmivaara, M. Kurunlahti, E. Kyllonen, T. Pienimaki, P. Nieminen, O. Tervonen and H. Vanharanta (2001) Cost effectiveness of periradicular infiltration for sciatica: subgroup analysis of a randomized controlled trial. Spine. 26(23): p. 2587-95.**

| Description of study: randomised controlled trial – level II evidence | |
|---|---|
| **Patient/population** | People with sciatica who had unilateral symptoms of 1 to 6 months duration. |
| **N** | Epidural injection of steroid plus local anaesthetic = 80<br>Epidural injection of saline = 80 |
| **Setting** | "Patients with sciatica were referred from the catchment area (population 360,000) of the University Hospital of Oulu." |
| **Intervention/indicator** | Epidural injection of steroid plus local anaesthetic (ESAI). |
| **Comparison/control** | Epidural injection of saline. |
| **Outcomes** | Quality of life, back and leg pain, disability, straight leg raising, lumbar flexion, tendon reflexes, sensibility, motor function and cost of medication and health care use. |
| **Inclusion Criteria** | "The inclusion criteria were unilateral pain radiating dermatomally from the back to below the knee that had lasted 3 to 28 weeks and leg pain intensity comparable at least with that of back pain. A positive dural tension sign (limited straight leg raising) was not a prerequisite for entry." |
| **Exclusion Criteria** | "The exclusion criteria were an earlier back operation, an application for early retirement, clinical depression, anticoagulation treatment, unstable diabetes, epidural injection during the preceding 3 months, pregnancy, allergy to any ingredients of the treatment agents,<br>and rare causes of sciatica such as synovial cysts and nondegenerative spondylolisthesis." |

| Study Validity | | |
|---|---|---|
| **Were there any conflicts of interest in the writing or funding of this study?** | No | "Conflict of interest category: 14."<br>Defined according to Spine Editorial Manager: "14. No benefits in any form have been or will be received from a commercial party related directly or indirectly to the subject of this manuscript." |
| **Does the study have a clearly focused question?** | Yes | "To test the efficacy of periradicular corticosteroid injection for sciatica." |
| **Is a RCT the appropriate method to answer this question?** | Yes | |
| **Does the study have specified inclusion/exclusion criteria?** | Yes | See above. |

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| **If there were specified inclusion/ exclusion criteria, were these appropriate?** | Yes | |
| **Did the study have an adequate method of randomisation?** | Yes | "The randomization process took place immediately before the intervention."<br>"The randomization process was based on a published list of random permutations with a block size of 16." |
| **Was allocation to intervention group concealed?** | Yes | "A person uninvolved in the study placed the assignments in sealed envelopes with running numbers. The envelopes were used in the order provided". |
| **Were patients blind to intervention group?** | Yes | "On their way to the infiltration procedure, each patient took an envelope to the Department of Radiology, where an authorized nurse filled a tape covered syringe with the treatment agent indicated therein. The assignments were thus masked to the patient, the physicians, and the radiologist giving the injection." |
| **Were investigators and care providers blind to intervention group?** | Yes | As noted above. |
| **Were outcome assessors blind to intervention group?** | Yes | As noted above.<br>"At the 2-week follow-up assessment, the attending physicians were asked to judge which of the two interventions had been used. Their determination was correct in 59% of the saline and 65% of the methylprednisolone/bupivacaine injection cases." |
| **Aside from the experimental intervention, were the groups treated the same?** | Yes | "Every patient was given back school instructions by the physiotherapist at the 2-week follow-up assessment. In cases of persisting sciatic pain, the patients received pain medication and traditional physiotherapy. In the case of severe sciatic pain from disc herniation and pronounced disability, the patient was referred to a neurosurgeon for discectomy evaluation. Each additional treatment and its cost to the patient were documented in the follow-up questionnaires." |
| **Was there sufficient duration of follow-up?** | Yes | Follow-up checks at 2 weeks, 1 month, 3 months, 6 months, and 1 year after the intervention |

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|---|---|---|
| **All outcomes were measured in a standard, valid and reliable way?** | Yes | Quality of life using the Nottingham Health Profile (NHP), back and leg pain using 100-mm visual analog scales, disability using the Oswestry Low Back Disability Questionnaire, straight leg raising (the position at which back or leg pain prevented further leg elevation recorded with a goniometer to the nearest 5°), lumbar flexion by the modified Schober measure (the difference between a 15-cm distance marked on the back of the patient in a standing position and the distance with the patient in full flexion), tendon reflexes, sensibility and motor function.<br><br>Economic Analysis:<br><br>Use and costs of health care services and help at home, based on the responses to the 4-week, 3-month, 6-month, and 1-year follow-up questionnaires; Cost of the infiltration procedure itself ($200) was not included in the saline group; MRI ($550) was included in the costs for both Groups; Days of sick leave and costs of medications obtained from the National Insurance Register; All additional treatments and visits to physiotherapists, osteopaths, and physicians, estimated from the data entered on the questionnaires and from medical records; For costs of physician and physiotherapist visits, the charges of the University Hospital were used ($55 for a physician visit and $38 for a physiotherapist visit); Data on back operations were gathered from the questionnaires and from medical records; Cost of a discectomy at the University Hospital ($3215) includes three inpatient postoperative days, with additional days costing $205; Home help, defined as help from the patient's spouse, children, relatives, or friends; Monetary value of 1 hour of home help, taken as the hourly wage of a municipal home helper ($9); Dollar costs were calculated at the 1998 exchange rate ($1 = 5.096 Finnish marks). |
| **Were outcomes assessed objectively and independently?** | Yes | Outcome assessors were blinded and validated measures were used. |
| **Was the study sufficiently powered to detect any differences between the groups?** | Yes | "Preliminary calculations showed a need for 68 patients in both treatment groups (β = 0.90, two-sided α = 0.05). The calculations were made for leg pain (the primary outcome) on the visual analog scale, using a clinically significant difference between the groups with a rating of 15 mm and assuming a standard deviation of 15%. After adjusting for a 20% loss to follow-up evaluation, 80 persons were enrolled for both groups. |
| **If statistical analysis was undertaken, was this appropriate?** | Yes | "Analysis of covariance (ANCOVA) was performed to compare the treatments. The adjusted change in scores for the different outcomes between adjacent follow-up assessments and baseline were calculated with 95% confidence intervals. Treatment effects were determined by reducing the adjusted scores of the saline group from those of the methylprednisolone group. In addition, to compare the efficacy of the two treatments, taking into account the total follow-up time, the area-under-the-curve method was used."<br><br>Means with confidence intervals and p-values for the difference between intervention and control means were reported. |
| **Were the groups similar at baseline with regards to key prognostic variables?** | Partial | "The affected level shown on MRI was more often the L4–L5 disc in the methylprednisolone group and the L5–S1 disc in the saline group (P=0.03). Days on sick leave before the intervention were significantly more in the saline group (P = 0.03), although the number of patients on sick leave was similar between the groups. These differences were considered clinically important confounders, and the scores of the treatment effects were adjusted accordingly." |
| **What percentage of the individuals recruited into each arm of the study dropped out?** | 2.5% treatment<br>0% control/ comparison | "In each treatment group, follow-up information was obtained at 2 weeks for 79 patients, 4 weeks for 80 patients, and 3 months for 79 patients. At the 6-month and 1-year follow-up assessments, information was obtained for 99% of the patients (n = 158). Two dropouts occurred in the steroid group: One patient moved away, and the other lived in the remote countryside." |

| | | |
|---|---|---|
| **Were all the subjects analysed in the groups to which they were randomly allocated (ie intention to treat analysis)?** | Not reported | |
| **Is the paper free of selective outcome reporting?** | Yes | |
| **Were the outcomes measured appropriate?** | Yes | |
| **What is the overall risk of bias?** | Low | *Most of the criteria have been fulfilled or where criteria have not been fulfilled it is very unlikely the conclusions of the study would be affected.* |

## Results

***Pain***

Immediately after treatment

ESAI: leg pain decreased by 61% and back pain by 52%,

Saline: leg pain decreased by 44% and back pain by 53%

Treatment effect for leg pain: 11.9 (CI, 2–21.8; P = 0.02)

No difference for back pain (P = 0.36)

At 2 weeks follow-up

Intensity of leg pain: ESAI = 39.1 Saline = 54.1 Difference = -12.5 (1.6 to 23.4) p=0.02

No difference found for intensity of back pain.

At 3 month follow-up

Intensity of back pain: ESAI = 26.2 Saline = 22.8 Difference = -12.2 (-23.5 to -1.0) p=0.03

No difference found for intensity of leg pain.

At 6 month follow-up

Intensity of leg pain: ESAI = 30.7 Saline = 21.6 Difference = -16.2 (-26.8 to -5.6) p=0.003

Intensity of back pain: ESAI = 22.6 Saline = 20.1 Difference = -13.5 (-24.6 to -2.4) p=0.02

At 1 year follow-up

Intensity of leg pain: ESAI = 23.9 Saline = 24.2 Difference = -5.3 (-15.7 to 5.0) p=NS

Intensity of back pain: ESAI = 18.8 Saline = 19.0 Difference = -8.4 (-18.9 to 2.1) p=NS

***Function***

At 2 weeks follow-up

Straight-leg-raising test (°): ESAI = 73 Saline = 70 Difference = 6 (1 to 12) p=0.03

Lumbar flexion (cm) : ESAI = 4.9 Saline = 4.8 Difference = 0.4 (0.1 to 0.8) p=0.05

No difference found for Owestry disability.

At 1 year follow-up

Oswestry disability: ESAI = 15.9 Saline = 16.3 Difference = -0.4 (-7.0 to 6.2) p=NS

Straight-leg-raising test (°): ESAI = 87 Saline = 84 Difference = 5 (-2 to 11) p=NS

Lumbar flexion (cm) : ESAI = 5.4 Saline = 5.4 Difference = 0.5 (-0.1 to 1.0) p=NS

No differences found at 4 weeks, 3 months or 6 months follow-up for all three outcomes.

***Quality of life***

At 1 year follow-up

Dimension of sleep on NHP: ESAI = 12.2 Saline = 10.0 Difference = -5.8 (-17.2 to 5.7) p=NS

Dimension of pain on NHP: ESAI = 19.6 Saline = 22.1 Difference = -3.9 (-16.0 to 8.2) p=NS

Dimension of mobility on NHP: ESAI = 10.5 Saline = 11.9 Difference = -0.4 (-7.0 to 6.2) p=NS

Dimension of energy on NHP: ESAI = 8.3 Saline = 8.0 Difference = 3.9 (-6.5 to 14.3) p=NS

Emotional reactions on NHP: ESAI = 4.4 Saline = 2.6 Difference = -1.8 (-7.2 to 3.5) p=NS

No differences found at 4 weeks, 3 months or 6 months follow-up for all three outcomes. These outcomes not measured at 2 weeks follow-up.

***Return to work***

At 1 year follow-up

Days of sick leave per month: ESAI = 1.9 Saline = 1.2 Difference = 0.6 (-1.2 to 2.4) p=NS

No differences found at 4 weeks, 3 months or 6 months follow-up for all three outcomes. These outcomes not measured at 2 weeks follow-up.

***Medication use***

1 year cumulative

Cost of medicine ($):ESAI = 46 Saline = 39 Difference = 7 (-39 to 46) p=NS

These outcomes not measured at 2 weeks, 4 weeks, 3 months or 6 months follow-up.

***Healthcare utilisation***

1 year cumulative

Home care ($): ESAI = 233 Saline = 476 Difference = -234 (-522 to 53) p=NS

Hospitalization:

Cost ($): ESAI = 876 Saline = 764 Difference = 152 (-413 to 717) p=NS

Mean days in hospital: ESAI = 1.01 Saline = 0.97 Difference = 0.1 (-0.7 to 0.8) p=NS

No. of surgically treated patients: ESAI = 18 Saline = 15

Visits to a doctor:

Cost ($): ESAI = 132 Saline = 142 Difference = -12 (-64 to 40) p=NS

No. of visits: ESAI = 2.2 Saline = 2.3 Difference = -0.2 (-1.1 to 0.6) p=NS

Therapy visits:

Cost ($): ESAI = 140 Saline = 214 Difference = -54 (-199 to 92) p=NS

No. of visits: ESAI = 3.7 Saline = 5.9 Difference = -1.7 (-6.3 to 2.9) p=NS

These outcomes not measured at 2 weeks, 4 weeks, 3 months or 6 months follow-up.

**Author's conclusions**

"The findings of the study indicate that both treatments had induced clinical improvements already at the 2-week follow-up assessment. Periradicular infiltration with a combination of methylprednisolone and bupivacaine 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 (Table 2), but not at later follow-up assessments. The saline injection was more effective for back pain as shown by the findings at the 3- and 6-month follow-up assessments, and for leg pain as shown at 6 months (Table 3)."

"The economic analysis showed that the methylprednisolone treatment had produced savings in costs of therapy visits and medications at 4 weeks, but other uses of resources and their respective costs and mean duration of sick leave were more or less equal in the two groups throughout the follow-up period (Tables 2–4)."

**Our comments/summary**

We consider this study to be well designed, with a low risk of bias. We consider the above conclusion to be justified. In terms of generalisability, we agree with the authors comment:
"Although this study was conducted in a tertiary care setting, in all likelihood the sample authentically represents patients with acute and subacute sciatica who did not undergo surgery."

**Table A4.3. Quality Appraisal of Systematic Review Addressing Complications of Cervical and Lumbar Epidural Injections**

**Study: Abdi S, Datta S, Trescot AM, Schultz DM, Adlaka R, Atluri SL, et al. Epidural steroids in the management of chronic spinal pain: a systematic review. Pain Physician 2007;10(1):185-212.**

| Description of study: systematic review of level II and lower level studies – level III-2 evidence | |
|---|---|
| **Patient/population** | Patients with chronic spinal pain (axial and radicular) in the neck and low back regions. |
| **N** | **Interlaminar epidural injections:** 13 randomised controlled trials. Number of participants is not specified. "Since there were multiple randomized trials evaluating lumbar pain (N=1) no prospective or retrospective evaluations were considered for inclusion."<br>**Transforaminal epidural injections:** 7 randomised controlled trials, 7 prospective evaluations and retrospective reports (number included is not specified). Number of participants is not specified.<br>**Caudal epidural injections:** 8 randomised controlled trials, 5 prospective evaluations and retrospective evaluations (number included is not specified). Number of participants is not specified.<br>*Please note that this review could not be used for information about effectiveness because recommendations were made based on all included studies, some of which did not meet our selection criteria. This review can only be used for information about complications of epidural injections because the findings from each included study were presented individually and those studies that did not meet our selection criteria could be excluded. Therefore only results about complications are reported in this appraisal.* |
| **Setting** | Not reported. |
| **Intervention/indicator** | "Three techniques of epidural injections (interlaminar, transforaminal, and caudal) with local anesthetic, steroid, or other drugs…" |
| **Comparison/control** | Not specified, but included studies used comparators such as saline, steroid and/or anaesthetic or morphine injected into various sites ie. epidural space, muscle, disc or ligament. Other interventions such as trigger point injections and discectomy were also used as comparators. |
| **Outcomes** | "The primary outcome measure was pain relief at various points in time. The secondary outcome measures were functional or psychological improvement, return to work, and complications. |
| **Inclusion Criteria** | Patients suffering with chronic spinal pain for at least 3 months.<br>"All the studies providing appropriate management with outcome evaluations of 3 months or longer and statistical evaluations were reviewed." |
| **Exclusion Criteria** | Not reported. |

| Study Validity | | |
|---|---|---|
| **Were there any conflicts of interest in the writing or funding of this review?** | No | "Funding: None. Conflict of Interest: None." |
| **Were reviewers blind to authors, institutions and affiliations?** | Not reported | |
| **Does the review have a clearly-focused question?** | Yes | |
| **Does the review have specified inclusion/exclusion criteria?** | Yes | As noted above. |

| | | |
|---|---|---|
| **Were 2 or more independent reviewers used for:**<br>**1. application of inclusion criteria to assess eligibility of studies?** | Yes | "All articles were reviewed by at least 3 authors in the group…" |
| **2. extraction of data from study reports?** | Not reported | |
| **3. appraisal of study quality?** | Not reported | |
| **If there were specified inclusion/ exclusion criteria, were these appropriate?** | Yes | |
| **Does the review document a comprehensive search strategy?** | Partial | An appropriate range of bibliographic databases were used and the reviewers searched for unpublished studies however subject headings and key words were not reported. |
| **Was the validity of included trials appraised using appropriate criteria?** | Yes | "For evaluating the quality of individual articles, we have used the criteria from the Agency for Healthcare Research and Quality (AHRQ) publication (95). For evaluation of randomized trials, criteria described by Cochrane Review Group for musculoskeletal disorders (96) also have been utilized." |
| **Is there a summary of the results of individual studies?** | Yes | There are summaries of the results of all prospective studies. |
| **Were the strengths and limitations of included studies and potential impact on the results discussed?** | Partial | |
| **If meta-analyses were conducted, was it reasonable to do so?** | Not applicable | |
| **If meta-analyses were conducted, was it done appropriately?** | Not applicable | |
| **Other** | | |
| **What is the overall risk of bias?** | Low | *Most of the criteria have been fulfilled or where criteria have not been fulfilled it is very unlikely the conclusions of the review would be affected.* |

**Results**

In this review, complications were listed for each included study. Of the included studies addressing complications, Huston et al, a cohort study, met our inclusion criteria.

"Huston et al (246) reviewed complications of cervical and lumbar selective nerve root injections (SNRs) in 151 consecutive patients who underwent a total of 306 SNRs. There were no major complications noted, and 91% of the patients had no side effects during the injection. The most common side effect noted was increased pain at the injection site after the injection, which was seen in 17.1% of the lumbar patients and 22.7% of the cervical patients."

| Author's Conclusions |
| --- |
| "Finally, all types of epidural steroid injections can be associated with complications and adverse events as described earlier. Therefore attention to detail and caution should be taken when performing any of the 3 techniques discussed in order to improve safety and minimize complications." |
| **Our comments/summary** |
| This review has a low risk of bias but we are only able to use information about complications of epidural injections using only one of many included studies. We are unable to use any of the other included studies because they do no meet our inclusion criteria. We agree with the authors conclusions. |