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Evidence Service

Spinal Injection Therapies: Radiofrequency Denervation

Evidence Review

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Spinal Injection Therapies: Radiofrequency Denervation

PLAIN LANGUAGE SUMMARY

Radiofrequency denervation (RFD) is sometimes used to treat persistent neck and back pain. RFD is the insertion of a needle next to joints in the spine. Electricity is then sent through the needle. The electricity destroys the nerve to the joint. When pain comes from that joint, the RFD stops the pain signals to the brain. Before doing RFD the doctor finds the right joint by numbing the suspected nerve(s) with an injection. Usually this is done twice or three times to be sure of where the pain is coming from. The other injections are either a different type of numbing solution or an inactive solution.

There is not enough evidence to assess the benefit and harm of RFD in the treatment of persistent pain in the neck or back.

Possible harms from RFD in the neck include minor numbness, unpleasant sensations and skin rash. For RFD in the lower back (sacroiliac) possible harms include short-term worsening of pain and pins and needles.

RFD can be done in different ways. Some researchers state that the way they do the injections and the RFD really matters. They say that the benefit of RFD that they have found will only happen to people who have RFD in exactly the same way. Others state that RFD can be used carefully in other ways, based on the doctor's experience and expertise.

Spinal Injection Therapies: Radiofrequency Denervation

EVIDENCE SUMMARY

Overview

The evidence for the effectiveness of radiofrequency denervation in the cervical, thoracic, lumbar and sacroiliac spine is either insufficient, inconclusive or conflicting (see glossary of findings below).

General Comments

CERVICAL FACET JOINTS:	All evidence syntheses identified were based on the same small RCT[1], but had conflicting results. The RCT was well-conducted and found a statistically significant effect with a large effect size. However, the small sample size, limits to the generalisability of the study, the fact that almost half of the patients receiving the intervention still had significant pain, and the lack of other high-level primary studies lead us to conclude that **the evidence of effectiveness of RFD on persistent cervical spinal pain is inconclusive.**
THORACIC FACET JOINTS:	The most recent high quality systematic review[2] identified found that **no evidence is available on the effectiveness of radiofrequency denervation** for the treatment of chronic mid back and upper back pain caused by thoracic facet joints.
LUMBAR FACET JOINTS:	A high quality systematic review[3] published in 2009 identified eight randomised controlled trials investigating the effectiveness of RFD for chronic lower back pain of lumbar facet joint origin. These studies present conflicting results and have a number of significant methodological and technical shortcomings that prevent an adequate assessment of the technique. As a result, **the existing evidence on RFD for chronic lower back pain is inconclusive.**
SACROILIAC JOINTS:	The most up-to-date synthesized source of evidence of RFD for chronic sacroiliac joint pain was a SR[4] based on three small observational studies, only two of which were relevant to this report. This review only included pain diagnosed by double-blocks. The only RCT[5] on this topic was a small study that included patients with pain diagnosed with single-blocks. The authors of this study note that further studies are needed to confirm these findings. Therefore, we conclude that **there is insufficient evidence to determine the benefits of radiofrequency denervation for relief of sacroiliac joint pain.**

In what clinical conditions is this intervention indicated for use?

CERVICAL:	The RCT included people with **chronic cervical pain of zygapophyseal joint origin**.
THORACIC:	There is **insufficient evidence** to answer this question.
LUMBAR:	The RCTs included patients suffering from **chronic lower back pain** with no indication for surgery.
SACROILIAC:	The SR and RCT used for this report, included patients with **sacroiliac joint pain diagnosed by double- and single-blocks**, respectively.

What is the effectiveness of this intervention on persistent pain in these conditions?	
CERVICAL:	The evidence is **inconclusive.**
THORACIC:	There is **insufficient evidence** to answer this question.
LUMBAR:	The evidence is **inconclusive.**
SACROILIAC:	There is **limited evidence of effectiveness** of pain relief.
What is the effect of this intervention on function, quality of life, return to work, medication use and the healthcare system?	
CERVICAL:	There is **insufficient evidence** to answer this question.
THORACIC:	There is **insufficient evidence** to answer this question.
LUMBAR:	There is **insufficient evidence** to answer this question.
SACROILIAC:	There is **insufficient evidence** to answer this question.
In what patient groups/conditions is use of this intervention contraindicated?	
CERVICAL:	There is **insufficient evidence** to answer this question.
THORACIC:	There is **insufficient evidence** to answer this question.
LUMBAR:	There is **insufficient evidence** to answer this question.
SACROILIAC:	There is **insufficient evidence** to answer this question.
What are the risks associated with this intervention?	
CERVICAL:	**Numbness or dysaesthesias** in the cutaneous territory of the coagulated nerves (not serious enough to require treatment), and **psoriatic rash** at the site of skin incision.
THORACIC:	There is **insufficient evidence** to answer this question.
LUMBAR:	There is **insufficient evidence** to answer this question.
SACROILIAC:	**Temporary worsening of pain** due to procedure-related pain and/or neuritis, and one transient non-painful buttock **paraesthesia**, but **no serious complications.**
What is the impact of training and/or experience of practitioners on patient outcomes?	
CERVICAL:	**Not reported** in the results of the RCT, but the authors state that their results cannot be generalised to apply to "patients whose pain is confirmed by less stringent criteria or who are treated with less exacting variants of the technique".[1]
THORACIC:	Not reported.
LUMBAR:	Not reported.
SACROILIAC:	**Not reported**, however, the systematic review states that RFD should be cautiously utilized based on "…physician's experience and technical abilities".[4]

Glossary of Findings	
Conflicting	The findings of the different studies identified conflict with each other (i.e. some studies find the intervention effective and other studies do not).
Inconclusive	We are unable to draw conclusions to answer questions based on this evidence. Reasons for this can include conflicting findings between different studies, or limited generalisability of results due to the small sample size or poor quality of the identified studies.
Insufficient	Little or no evidence exists to answer this question.
Limited evidence of effectiveness	There is some evidence of effectiveness but not enough to be sure. More high quality studies are needed before conclusions can be drawn.

BACKGROUND

Radiofrequency denervation has been used to treat patients with chronic pain of spinal origin. It is known by many names including radiofrequency neurotomy, percutaneous radiofrequency facet denervation, percutaneous facet coagulation, percutaneous radiofrequency neurotomy, radiofrequency facet rhizotomy, and radiofrequency articular rhizolysis. Radiofrequency denervation has been used for pain relief in the neck (cervical) and upper (thoracic) and lower (lumbar and sacroiliac) back.

An anaesthetic block of the nerve where the pain originates is required for confirmation of diagnosis and confirmation of the target location. X-ray fluoroscopy is used to guide an insulated electrode with an exposed tip into the spinal area where the electrode is positioned parallel to the nerve supplying a painful facet joint.[6] A current is passed through the electrode destroying the adjacent tissue, including the target nerve, so that transmission of pain signals from this nerve is interrupted.[6]

In order to develop and update policies for the use of radiofrequency denervation in patients with chronic pain, the Transport Accident Commission and WorkSafe Victoria (TAC/WSV) Health Services Group requested a systematic review of the evidence of effectiveness of this intervention.

An Evidence Review was completed in April 2009 but not finalised due to the pending publication of a Cochrane Review update, which would potentially be a high-quality source of evidence that synthesised studies not included in previous systematic reviews and evidence based guidelines. The update of the Cochrane Review was an update of format rather than content, so the TAC/WSV requested that the Evidence Service update the Radiofrequency Denervation Evidence Review produced in April 2009.

QUESTIONS

This review sought to find the most up-to-date, high quality source of evidence to answer the following questions for each anatomical location (cervical facet joints, thoracic facet joints, lumbar facet joints, and sacroiliac joints):

- In what conditions is this intervention indicated?
- What is the effectiveness of this intervention on persistent spinal pain in these conditions?
- What is the effect of this intervention on function (physical, psychological, social), 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?
- What is the impact of training and/or experience of practitioners on patient outcomes?

METHODS

Methods are outlined briefly below. More detailed information about the methodology used to produce this report is available in Appendices 1 and 2. All appendices are located in the Technical Report accompanying this document.

The original searches used in the April 2009 Evidence Review were rerun from the date of the last search onwards to identify recent synthesised research (i.e. evidence-based guidelines (EBGs), systematic reviews (SRs), health technology assessments (HTAs)), and any available randomised controlled trials (RCTs) and controlled clinical trials (CCTs). A comprehensive search of the internet, relevant websites and electronic health databases was also undertaken. The inclusion and exclusion criteria from the April 2009 Evidence Review were applied to the search results.

For each anatomical location, the EBGs, SRs, HTAs, RCTs or CCTs meeting the selection criteria were screened to identify the most up-to-date and comprehensive source of evidence, which was then critically appraised to determine whether it was of high quality. If necessary, the screening, selection and appraisal process was repeated for additional sources of evidence until the most recent, comprehensive and high quality source of evidence was identified for each anatomical location. Findings from the best available source of evidence were compared to other evidence sources for consistency of included references and findings.

The available synthesised evidence was mapped (see Table 2), and the algorithm in Table 1 was followed to determine the next steps necessary to answer the clinical questions.

Table 1. Further action required to answer clinical questions

<table>
<tr><th colspan="5">Is there any synthesised research available? (e.g. EBGs, HTAs, SRs, RCTs)</th></tr>
<tr><th colspan="3">Yes</th><th colspan="2">No</th></tr>
<tr><th colspan="3">Is this good quality research?</th><th colspan="2">Are RCTs available?</th></tr>
<tr><th colspan="2">Yes</th><th>No</th><th>Yes</th><th>No</th></tr>
<tr><th colspan="2">Is it current (within 2 years)?</th><td rowspan="2"></td><td rowspan="2"></td><td rowspan="2"></td></tr>
<tr><th>Yes</th><th>No</th></tr>
<tr><td>No further action</td><td>Update existing SR</td><td>Undertake new SR</td><td>Undertake new SR</td><td>Consider looking for lower levels of evidence</td></tr>
</table>

Data on characteristics of all included studies were extracted and summarised (see Appendix 5). The most recent, comprehensive, high quality EBG or systematic review for each anatomical location was used to address the questions posed above.

RESULTS

An initial search of electronic databases conducted in November 2008, and update search in May 2010 yielded 1,027 potentially relevant journal articles. After reviewing the title, abstract or full text, 3 EBGs, 25 SRs and HTAs, and 8 RCTs were found that met the selection criteria. Internet searches yielded an additional 8 EBGs.

In total, 11 EBGs, 25 SRs & HTAs, and 8 RCTs met our inclusion and exclusion criteria (see Table 2).

Table 2. Evidence map of identified studies by study-type and anatomical location

Anatomical Location	Synthesised Studies		Primary studies	TOTAL
	EBGs	SRs & HTAs		
Cervical	8	15	1 RCT	24
Thoracic	0	4	0	4
Lumbar	6	14	6 RCTs	26
Sacroiliac	1	5	1	7
TOTAL*	11	25	8	44

**columns may not add up to totals as some EBGs and systematic reviews identified evaluated RFD in more than one anatomical area*

Results are reported below by anatomical location.

1. CERVICAL FACET JOINTS

Evidence identified

Searches yielded a total of 24 studies[1,7-29] of RFD in the cervical spine published between 1996 and 2010. Numbers for by study design are reported in Table 2. A summary of these studies can be found in Appendix 4, Table A4.1.

The effectiveness of RFD on cervical spinal pain has been assessed in numerous synthesised studies. The three most up-to-date synthesised studies were critically appraised, two were found to have insufficient information to determine the risk of bias[8,28] and the other[15] to have a moderate risk of bias (see Appendix 5). All of the identified synthesised evidence used a single RCT[1] as the predominant or only source of evidence. However, despite being based on the same study, the SRs, EBGs and HTAs reached differing conclusions around the efficacy and appropriate use of RFD for cervical spinal pain (see summary of studies, Appendix 4, Table A4.1). Because of this, the RCT by Lord et al[1] has been critically appraised and is used for this section of the report (see Table 3).

Table 3. Key information from most recent, high quality primary study – CERVICAL FACET JOINTS

Lord SM, Barnsley L, Wallis BJ, McDonald GJ, Bogduk N. Percutaneous radio-frequency neurotomy for chronic cervical zygapophyseal-joint pain. N Engl J Med. 1996 Dec 5;335(23):1721-6.	
Study design	Randomised Controlled Trial
Scope	**Patient/population:** N=24 (9 males, 15 females; mean age 43), 12 in intervention arm and 12 in control arm **Conditions indicated for use:** patients with chronic neck pain (>3 months) due to MVA who failed conventional treatment, and the cervical zygapophyseal joint had been confirmed as the origin of pain through placebo controlled, diagnostic, local anaesthetic blocks. **Intervention:** RFD, two to three lesions in two locations, where the electrode tip was raised to 80°C for 90 seconds during lesioning **Control:** identical procedure, but electrode temperature maintained at 37°C **Outcomes assessed:** pain relief (visual analogue scale, McGill Pain Questionnaire), psychological distress, restoration of 4 activities of daily living as selected by each patient, numbness.
Effectiveness RFD on chronic neck pain of cervical zygapophyseal joint origin	"The median time to the return of at least 50 percent of the preoperative level of pain was 263 days in the active-treatment group and 8 days in the placebo group (P=0.04 by the Mantel–Haenszel test)"
Effect of RFD on function (physical, psychological, social), quality of life, return to work, medication use and healthcare utilisation	The authors found RFD to be clinically and statistically more efficacious than the control intervention. Their definition of a successful treatment was complete relief of pain with restoration of desired activities of daily living (ADL) (each patient chose four ADLs they would most like restored). The ADLs selected most often included: return to work; housework (laundry, vacuuming, gardening); driving or travelling long distances; playing sports; having sex; and, lifting or caring for children. However, restoration of chosen ADLs was reported combined with pain relief rather than individually. The authors note that they collected psychological distress measures at baseline, but do not report further on these, and do not report results for any other aspects of function, quality of life, return to work, medication use or healthcare utilisation.
Risks associated with RFD	Five patients in the active treatment group experienced numbness or dysaesthesias in the cutaneous territory of the coagulated nerves, patients did not consider this to be serious enough to require treatment. One patient experienced a psoriatic rash starting at the point of skin incision.
In what patient groups/conditions is RFD contraindicated?	Not reported
What is the impact of training and/or experience of practitioner on patient outcomes?	The authors do not mention the impact of training or practitioner experience on patient outcomes, but state that "technical precision and adequate denaturation of the target nerves are paramount during surgery". A very specific RFD technique is used for this study and the authors state that their "results apply only to patients responsive to double-blind, placebo-controlled, diagnostic blocks whose treatment involves multiple lesions of the target nerves. The results cannot be generalized to apply to patients whose pain is confirmed by less stringent criteria or who are treated with less exacting variants of the technique."

Conclusion/Recommendation	"In patients with chronic cervical zygapophyseal-joint pain confirmed with double-blind, placebo-controlled local anesthesia, percutaneous radio-frequency neurotomy with multiple lesions of target nerves can provide lasting relief."..."We found that radio-frequency neurotomy provided lasting, complete relief, but only in a moderate proportion of patients. Nevertheless, as shown in this study and previously, such relief can last for months to over a year, and if pain recurs the relief can usually be reinstated by repeating the procedure."
Recommendation category	positive
Quality assessment results	This RCT was well conducted and considered to have a low risk of bias (see Appendix 5 for quality appraisal)
Our comments/summary	**Overall this study provides limited evidence of benefit of radiofrequency Denervation for relief of chronic neck pain** This paper has had mixed reviews in the synthesized research due to issues of potential unblinding, small sample size and differences in groups at baseline - this is countered by arguments of it being unethical to subject a large group to an invasive sham procedure, and the difficulty of successfully blinding invasive procedures. The authors present a well conducted RCT with low risk of bias, and with results suggesting the benefit of using radiofrequency denervation for relief of chronic neck pain as well as restoration of selected ADLs in a moderate proportion of patients (7 out of 12 treated patients remained pain free at 27 weeks). This study reported a statistically significant beneficial effect with a large effect size. Based on this, some authors of synthesised studies may conclude that RFD is effective. However, due to the small sample size (n=24); the fact that of the 12 patients in the intervention group, 5 still had pain; and the very specific diagnostic method and RFD technique used, others may consider it necessary for more primary research to be undertaken before the results can be generalised and decisions made about the effectiveness of RFD for cervical spinal pain. In the absence of other, and large, well conducted trials, RFD should be recommended cautiously, bearing in mind the limitations in study methodology as well as generalisability described by the authors “Our results apply only to patients responsive to double-blind, placebo-controlled, diagnostic blocks whose treatment involves multiple lesions of the target nerves. The results cannot be generalized to apply to patients whose pain is confirmed by less stringent criteria or who are treated with less exacting variants of the technique.”

Findings

Due to conflicting findings of SRs and EBGs that are based on the same RCT (Lord et al)[1], the small sample size of this RCT, and the lack of other high-level primary studies (such as RCTs); there is insufficient evidence to determine the effectiveness of radiofrequency denervation for relief of chronic neck pain.

2. THORACIC FACET JOINTS

Evidence identified

We identified four systematic reviews[2,10,18,23] addressing radiofrequency denervation for the treatment of chronic pain of thoracic origin (Table 2). Characteristics and key findings of these studies are presented in Appendix 4, Table A4.2. There were no EBGs, HTAs, RCTs or CCTs for this intervention that met our selection criteria.

The most comprehensive, rigorous and up-to-date source of synthesised research regarding radiofrequency denervation for the treatment of chronic pain of thoracic origin was a systematic review by Atluri et al.[2] published in 2008. Table 4 shows key information extracted from this study, a quality appraisal can be found in Appendix 5, Table A5.5.

Atluri et al[2] identified two retrospective evaluations. These studies did not have adequate comparative groups, did not diagnose with controlled blocks, had only a small number of participants, and did not have adequate outcome measures or statistical analysis. Using the Agency for Healthcare Research and Quality (AHRQ) methodology for quality assessment of observational studies, the two included studies were found to be of low quality and subsequently excluded from the review.

There is insufficient evidence available to provide any information on the effectiveness of radiofrequency denervation for persistent mid and upper back pain of thoracic facet joints origin.

Table 4. Key information from most up-to-date, high quality study – THORACIC

Atluri S, Datta S, Falco FJE, Lee M. Systematic review of diagnostic utility and therapeutic effectiveness of thoracic facet joint interventions. Pain Physician. 2008;11(5):611-29.	
Study design	Systematic review
Scope	The study aimed to address the clinical utility of diagnostic and therapeutic thoracic facet joint interventions in patients with chronic mid and upper back pain. **Condition indicated for use:** patients with chronic upper back pain
Effectiveness of RFD in persistent pain	Not reported
Effect of RFD on function (Physical, psychological, social), quality of life, return to work, medication use, healthcare utilisation	Not reported
Risks associated with RFD	Not reported
In what patient groups/conditions is RFD contraindicated?	Not reported
What is the impact of training and or experience of practitioner on patient outcomes?	Not reported
Conclusion/Recommendation	"The literature search revealed 34 studies for radiofrequency Neurotomy. Of these, 2 studies were identified which showed percutaneous facet denervation of medial branches. However, both of them failed to meet inclusion criteria, with low methodological quality." "The disadvantages of both the studies include retrospective evaluation without a comparative group, lack of diagnosis by controlled blocks, small number of patients, without adequate outcome measures, and statistical analysis." "Based on the review of the included therapeutic studies described herein, no evidence synthesis is available for thoracic radiofrequency neurotomy."
Recommendation category	Insufficient evidence
Quality assessment results	Low risk of bias
Our comments/summary	The study is a well conducted systematic review with a low risk of bias. It shows that only two low quality observational studies have assessed RFD. The systematic review authors conclude that no evidence on the therapeutic effectiveness of radiofrequency denervation for thoracic facet joint pain has been identified.

Findings

No evidence is available on the effectiveness of radiofrequency denervation for the treatment of chronic mid back and upper back pain of thoracic facet joint origin.

3. LUMBAR FACET JOINTS

Evidence identified

Literature searches identified 26 studies,[3,6,8,10,11,14,16-19,22,23,25,30-42] published between 2001 and 2010, assessing the effectiveness of radiofrequency denervation for the treatment of chronic pain of lumbar origin (Table 2). Key information extracted from these studies is presented in Appendix 4, Tables A4.3-A4.9.

We first considered the most recent source of synthesized evidence, an EBG for chronic pain management published in April 2010 by the American Society of Anesthesiologists and the American Society of Regional Anesthesia and Pain Medicine[8]. However, the quality appraisal process raised a number of methodological issues in the study. After seeking clarifications from the guidelines' authors, uncertainties remained on several important methodological points. Results of the quality assessment can be found in Appendix 5, Table A5.1.

The most rigorous and up-to-date source of synthesised evidence was a systematic review conducted in 2009 by Chou et al.[3] for the American Pain Society clinical practice guidelines. The study is a general review of nonsurgical therapies for low back pain covering a wide range of therapeutic techniques. Table 5 presents the study characteristics and key findings on radiofrequency denervation interventions. A quality appraisal can be found in Appendix 5, Table A5.6, and detailed results from the included RCTs are available in Appendix 4, Tables A4.4-A4.9.

In summary, Chou et al., a high quality systematic review, identified eight randomised controlled trials evaluating radiofrequency denervation. The RCTs presented conflicting results and methodological shortcomings which prevented the authors from conducting an adequate and reliable evaluation of RFD. Similarly, we were unable to conduct a meta-analysis due to unreported standard errors in some of the studies and the use of different scales for pain measurement.

The current available evidence on the effectiveness of radiofrequency denervation for chronic pain of lumbar facet joint origin remains inconclusive.

Table 5. Key information from most up-to-date, high quality study – LUMBAR

Chou R, Atlas SJ, Stanos SP, Rosenquist RW. Nonsurgical interventional therapies for low back pain: a review of the evidence for an American Pain Society clinical practice guideline. Spine. 2009;34(10):1078-93.	
Study design	Systematic review
Scope	The study is a SR and EBG that aims to assess the benefits and harms of nonsurgical interventional therapies for low back pain and radicular pain. In this table, only findings on radiofrequency denervation are reported. **Condition indicated for use:** Chronic low back and radicular pain
Effectiveness of RFD in persistent pain	Not reported
Effect of RFD on function (Physical, psychological, social), quality of life, return to work, medication use, healthcare utilisation	Not reported
Risks associated with RFD	Not reported
In what patient groups/conditions is RFD contraindicated?	Not reported
What is the impact of training and or experience of practitioner on patient outcomes?	Not reported
Conclusion/Recommendation	"It is not clear if clinical trials of RFD interventions targeting specific anatomical sources of back pain have failed to demonstrate efficacy because of inaccurate diagnosis methods, because the intervention truly does not work, or because the trial evaluated technically inadequate procedures." "There is insufficient (poor) evidence from randomized trials to reliably evaluate radiofrequency denervation."
Recommendation category	Insufficient evidence
Quality assessment results	Low risk of bias
Our comments/summary	The study is a well conducted systematic review with low risk of bias. Of 8 RCTs identified in the study, 4 have been classified as higher quality and only one uses controlled facet joint blocks to select patients and an ablation technique believed to be optimal. The authors of the systematic review point out that more rigorous randomised trials are needed to guide radiofrequency denervation appropriate use for the treatment of low back pain.

Findings

The most up-to-date synthesized source of evidence of RFD for chronic pain of lumbar origin was based on 8 randomised controlled trials. These studies present significant methodological and technical limitations. Therefore, it is not possible to draw any solid conclusions from their results on the effectiveness of radiofrequency denervation for the treatment of chronic low back pain.

4. SACROILIAC JOINTS

Evidence identified

Searches yielded 7 studies[4,5,8,10,18,43,44] of RFD of the sacroiliac joint published between 2005 and 2010. Numbers by study design are reported in Table 2. A summary of these studies can be found in Appendix 4, Table A4.10.

The effectiveness of RFD on spinal pain originating in the sacroiliac joint has been assessed in six synthesised studies.[4,8,10,18,43,44] The most up-to-date synthesised study[8] was critically appraised and found to have insufficient information to assess the risk of bias (see Appendix 5, Table A5.1).

The next most recent study by Rupert et al[4] was found to have low to moderate risk of bias (see Appendix 5, Table A5.7). This SR is based on three observational studies, and excludes the only RCT[5] available on this topic due to the use of a single diagnostic block to diagnose sacroiliac joint pain. The review authors considered that "without the use of double comparative blocks, one cannot reliably eliminate false-positive responders", however the authors acknowledge that this is not a "universally accepted criterion".

For the purposes of this Evidence Review, the inclusion criteria allow diagnosis with single, double or controlled medial branch block or intra-articular injection (see Appendix 2, Table A2.1), therefore, the RCT by Cohen et al[5] was quality appraised (see Appendix 5, Table A5.8) and is used in addition to the SR by Rupert et al[4] for reporting purposes in this section.

Table 6. Key information from most up-to-date, high quality synthesised study – SACROILIAC JOINT

Rupert MP, Lee M, Manchikanti L, Datta S, Cohen SP. Evaluation of sacroiliac joint interventions: A systematic appraisal of the literature. Pain Physician. 2009;12(2):399-418.	
Study design	Systematic Review
Scope	**Patient/population:** people with sacroiliac joint pain (systematic review of three observational studies: n=22, n=9, n=9) **Conditions indicated for use:** sacroiliac joint pain **Intervention:** diagnostic and therapeutic interventions (including intra-articular sacroiliac joint injections and radiofrequency neurotomy of the nerve supply of the sacroiliac joint) **Outcomes assessed:** pain relief measured at various time points and lasting at least six months. Secondary outcome measures were functional improvement, psychological improvement, return-to-work, opioid use, and complications
Effectiveness RFD on sacroiliac joint pain	This review found limited evidence for the effectiveness of RFD on short- and long- term pain relief
Effect of RFD on function (physical, psychological, social), quality of life, return to work, medication use and healthcare utilisation	Although the review set out to look at some of these outcomes, results were not reported
Risks associated with RFD	Not reported
In what patient groups/conditions is RFD contraindicated?	Not reported
What is the impact of training and/or experience of practitioner on patient outcomes?	Therapeutic sacroiliac joint interventions “should be cautiously utilized based on strict selection criteria, in parallel with the physician’s experience and technical abilities”
Conclusion/Recommendation	"For radiofrequency neurotomy, the indicated evidence is Level II-3 (limited). The recommendations based on Guyatt et al’s (62) criteria are 2B/a weak recommendation for radiofrequency neurotomy for sacroiliac joint pain... considering that there is no other viable alternative to managing sacroiliac joint pain in patients refractory to corticosteroid injections, the judicious use of this technology in carefully selected patients appears warranted. But it is equally clear that further studies are needed to both refine the selection criteria and improve the technology"
Recommendation category	positive
Quality assessment results	low to moderate risk of bias
Our comments/summary	**Limited evidence of benefit of radiofrequency Denervation for relief of chronic sacroiliac joint pain** Overall there is limited evidence of the benefit of RFD for relief of chronic sacroiliac joint pain. This SR is based on three observational studies (n=22, n=9, n=9), the largest of these involved pulsed RFD, which is not relevant to this report.

Table 7. Key information from most recent, high quality primary study – SACROILIAC JOINT

Cohen SP, Hurley RW, Buckenmaier CC, 3rd, Kurihara C, Morlando B, Dragovich A. Randomized placebo-controlled study evaluating lateral branch radiofrequency denervation for sacroiliac joint pain. Anesthesiology. 2008;109(2):279-88.	
Study design	Randomised Controlled Trial
Scope	**Patient/population:** (RFD group n=14, control group n=14) **Conditions indicated for use:** people with injection-diagnosed sacroiliac joint pain **Intervention:** RFD procedure with current **Comparison:** Placebo – RFD procedure without current **Outcomes assessed:** primary outcome: pain; secondary outcomes: function, reduction in analgesic medications, global perceived effect (GPE), duration of pain relief, composite successful outcome, and complications.
Effectiveness RFD on sacroiliac joint pain	There was better short-term sacroiliac pain relief in the RFD group than the placebo group. It is important to note that the authors acknowledge that larger, multicentre studies with long-term follow-up and comprehensive outcome measures are needed to confirm these findings, further establish safety, and determine how best to identify candidates for this treatment. We conclude that there is insufficient evidence about the effectiveness of radiofrequency denervation for sacroiliac joint pain.
Effect of RFD on function (physical, psychological, social), quality of life, return to work, medication use and healthcare utilisation	There was better short-term improvement in function and reduction in medication use in the RFD group than the placebo group. Given that Cohen et al conclude that larger, multicentre studies with long-term follow-up and comprehensive outcome measures are needed to confirm these findings, further establish safety, and determine how best to identify candidates for this treatment, we conclude that there is insufficient evidence about the effectiveness of radiofrequency denervation for these outcomes. Quality of life, psychological and social function, return to work and healthcare utilisation outcomes were not reported in any of the evidence identified by our search.
Risks associated with RFD	The majority of patients reported temporary worsening pain lasting between five and ten days after the procedure, which was attributed to procedure-related pain and/or temporary neuritis. The authors found that there were no serious complications reported in either the placebo or the radiofrequency denervation groups. In the radiofrequency treatment group, one patient reported transient nonpainful buttock paresthesias that resolved without therapy. The other studies do not report risks associated with radiofrequency denervation in sacroiliac joints.
In what patient groups/conditions is RFD contraindicated?	Not reported
What is the impact of training and/or experience of practitioner on patient outcomes?	Not reported
Conclusion/Recommendation	"…the results of this placebo-controlled study provide preliminary support for the use of radiofrequency denervation to treat presumptive sacroiliac joint

	pain. Larger, multicenter studies with long-term follow-up and comprehensive outcome measures are needed to confirm our findings, further establish safety, and determine how best to identify candidates for this treatment."
Recommendation category	positive
Quality assessment results	Low risk of bias
Our comments/summary	The authors present a well conducted RCT, with low risk of bias, and with results suggesting the benefit of using RFD for short term (1 month) relief of sacroiliac pain, function, GPE, medication reduction and duration of pain relief. It is important to note that p values were not presented for the findings at the 3 month time point; therefore it is difficult to draw conclusions about these data. The trial authors acknowledge that larger, multicenter studies with long-term follow-up and comprehensive outcome measures are needed to confirm these findings, further establish safety, and determine how best to identify candidates for this treatment.

Findings

The most up-to-date synthesized source of evidence of RFD for chronic sacroiliac joint pain was based on three, small observational studies, only two of which were relevant to this report. This SR only included pain diagnosed by double-blocks. The authors of the review concluded that there was limited evidence of benefit of RFD.

The only RCT on this topic was a small study that included patients with pain diagnosed with single-blocks. The authors of this study note that further studies are needed to confirm these findings.

There is insufficient evidence to determine the benefits of RFD for relief of sacroiliac joint pain.

DISCUSSION & CONCLUSION

As a number of evidence syntheses assessing the effectiveness of radiofrequency denervation were identified, a pragmatic yet rigorous approach was taken where the best quality, most up-to-date source of synthesised evidence for each anatomical location was used to answer the review questions where possible.

As the evidence syntheses addressed their own specific questions rather than the questions that are the focus of this review, not all of the review questions could be answered. Also, when using synthesised evidence, 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.

A key finding of this review is the inconsistency in the findings of primary studies and in the conclusions drawn by authors of synthesised evidence. Some RCTs report that radiofrequency denervation is effective, others that their results are inconclusive, and a third group find that there is no effect. Reviews vary in the primary studies that they include and in the conclusions they draw from the same studies.

RFD for persistent pain of cervical facet joint origin:

We found 23 relevant evidence syntheses[7-29] and one small RCT.[1] All of the synthesised evidence used the single RCT as the main or only source of evidence. Some authors concluded that RFD is effective based on positive results of the RCT, others concluded that this small RCT is not strong enough evidence on its own to be able to draw conclusions about the effectiveness of RFD. The authors of the RCT also cautioned against generalising the results of their study. We conclude that there is insufficient evidence to determine the effectiveness of cervical facet joint RFD for relief of persistent pain, function, quality of life, return to work, medication use or healthcare utilisation.

RFD for persistent pain of thoracic facet joint origin:

The most up-to-date systematic review[2] on treatment options for thoracic facet joint pain was unable to identify any evidence on the effect of radiofrequency denervation. An evaluation of the effectiveness of RFD for chronic pain of thoracic facet joint origin is yet to be performed.

RFD for persistent pain of lumbar facet joint origin:

The most up-to-date systematic review[3] on RFD for chronic pain of lumbar origin was based on 8 randomised controlled trials. Chou et al.[3] demonstrated that all of these studies presented serious methodological and technical issues that undermined the internal and external validity of their results. It is therefore not possible to present any definitive conclusions on the potential benefit or harm of RFD for this indication.

RFD for persistent pain of sacroiliac joint origin:

We found six relevant synthesised studies[4,8,10,18,43,44] and one small RCT.[5] The most recent high-quality synthesised source of evidence[4] was based on three, small observational studies (only two of which were relevant to this report) and excluded the only available RCT due to the diagnostic procedure used. All other synthesised evidence pre-dated the RCT. Authors of the SR concluded that

evidence of the effectiveness of RFD was limited and gave a weak recommendation for its use. The authors the RCT noted that further studies are needed to confirm their findings. We conclude that there is insufficient evidence to determine the effectiveness of sacroiliac joint RFD for relief of persistent pain, function, quality of life, return to work, medication use or healthcare utilisation.

Overall, when considering the sources of evidence used to answer the review questions for each anatomical area, there is insufficient evidence to provide information about the effects of radiofrequency denervation.

DISCLAIMER

CONFLICT OF INTEREST

The TAC/WSV Evidence Service is provided by the National Trauma Research Institute. The NTRI does not accept funding from pharmaceutical or biotechnology companies or other commercial entities with potential vested interest in the outcomes of systematic reviews.

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

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Transport Accident Commission & WorkSafe Victoria

Evidence Service

Spinal Injection Therapies: Radiofrequency Denervation

Technical Report: Appendices 1-5

October 2010

Driss Ait Ouakrim, Emma Donoghue

Accompanying documents to this report	
Title	**Report number**
Spinal Injection Therapies: Radiofrequency Denervation – Evidence Review	0910-002-R4

A joint initiative of

INTRODUCTION

This technical report is a companion document to "Spinal Injection Therapies: Radiofrequency Denervation, Evidence Review". It contains detailed information about the methods used in the development of the Evidence Review, summaries of the studies included in the review, and quality appraisal results for the most recent and/or most relevant included studies for each anatomical location.

CONTENTS

APPENDIX 1: REVIEW PROCESS

A two-staged approach was undertaken.

STAGE 1

Identify evidence available for each intervention

• Rerun search used in original report from initial search date to current in health databases, websites and on the internet, limit to EBGs, HTAs, SRs, RCTs and controlled clinical trials (CCTs)

• Apply inclusion and exclusion criteria used in initial report

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

Decide on actions for Stage 2

• Map available evidence (as per Table A1.1)

• Identify whether sufficient high level evidence exists to answer questions or identify what further action needs to be taken (see algorithm in Table A1.2).

STAGE 2

Address further actions identified.

Table A1.1. Map of available evidence

Anatomical Location	Synthesised Studies		Primary studies	TOTAL
	EBGs	SRs & HTAs		
Cervical				
Thoracic				
Lumbar				
Sacroiliac				
TOTAL				

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

<table>
<tr><td colspan="4">Is there any synthesised research available? (e.g. EBGs, HTAs, SRs, 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"></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>Consider looking for lower levels of evidence</td></tr>
</table>

APPENDIX 2: METHODS

TAC/WSV staff assisted in the development of search terms and inclusion and exclusion criteria for the initial Evidence Review produced in April 2008. The original Evidence Review from April 2008 was used as the basis for methods used in the development of this report. The same terms and criteria were used for the updated Evidence Review with the exception of the time period, as we were only looking for publications from 2008 to 2010 (see Tables A2.1-A2.3). The results of our searches were combined with those reported in the previous review, and the same questions and anatomical locations were the focus of the review. Two relevant quality appraisals from the previous review were modified slightly and used again in this report.

Inclusion and exclusion criteria

Inclusion and exclusion criteria were established *a priori* (Table A2.1) and were applied by two reviewers, any discrepancies were resolved through discussion.

Table A2.1 Inclusion and Exclusion criteria

Patient/ population	**Inclusion:** Patients with persistent pain • Spinal origin (cervical, thoracic, lumbar), or from the sacroiliac joint • Diagnosed with a single, double or controlled medial branch block or intra-articular injection • Following trauma, or arthritis resulting from trauma • As defined by trialists
	Exclusion: Non-persistent spinal pain; peripheral, non-spinal pain; spinal or sacroiliac pain in which no diagnostic nerve block undertaken; non-traumatic pain (e.g. cancer pain); trigeminal neuralgia.
Intervention/ indicator	The review included interventions administered at any stage of the management of persistent pain (e.g. first-line, second-line, when all else fails, as an adjunct to therapy).
	Inclusion: Radiofrequency Denervation, also known as Radiofrequency Neurotomy, Percutaneous Radiofrequency Facet Denervation, Percutaneous Facet Coagulation, Percutaneous Radiofrequency Neurotomy, Radiofrequency Facet Rhizotomy, Radiofrequency Articular Rhizolysis Non-pulsed Radiologically guided
	Exclusion: Intradiscal procedures, intramuscular procedures, neuromyotomy, pulsed radiofrequency denervation, non-radiologically guided.
Comparison/ control	**Inclusion:** Sham/placebo procedure (e.g. injection of saline), usual care (e.g. analgesics, physiotherapy, medical consultations), another active procedure targeting the same structure.
	Exclusion: Nil
Outcomes	**Inclusion:** Pain measures, physical function (e.g. mobility, disability), psychological outcomes (e.g. depression), social functioning (e.g. social roles), activities of daily living, quality of life, return to work, medication use, healthcare utilisation, adverse events.
	Exclusion: Nil
Setting	**Inclusion**: Any healthcare setting (e.g. acute, subacute, rehabilitation, community).
	Exclusion: Nil
Study Design	**Inclusion:** Evidence-based guidelines, systematic reviews, health technology assessments, randomised controlled trials and controlled clinical trials.
	Exclusion: Non-EBGs, non-systematic reviews, cohort studies, case-control studies, case series, editorials, letters, commentaries.
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

Searches undertaken

Search methods

Evidence Based Guidelines (EBGs) are generally published as electronic 'stand alone' documents on the internet rather than papers in peer reviewed journals. This searching update repeated the methods of the previous November 2008 search processes. We searched first in standard health databases, then in websites which are known to publish high-quality research and guidelines and finally in a general search engine, as follows;

Search strategies in electronic databases

Standard systematic review strategies, as outlined below in the Medline search example, were used to identify existing reviews and trials. Additional reviewing of the references from the searches identified EBGs.

Internet searches to identify relevant websites

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 (egg. accident compensation groups) known to contain evidence-based resources. Additional websites of specific relevance (egg. pain associations) were revisited for publications from 2008 onwards

Website searches to identify relevant EBGs

Where an internal search engine was available, websites were searched using the following search string - (radiofrequency OR coagulation) AND (denervation OR neurotomy OR ablation) AND (pain) (med* OR nerve OR branch OR dorsal OR posterior) AND (block) AND (pain) If no search engine was available, lists of guidelines, publications or other resources identified on the site and scanned for relevant documents on radiofrequency denervation.

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, published on Google in the last year and was used to identify EBGs for radiofrequency denervation. (radiofrequency OR coagulation) AND (denervation OR neurotomy OR ablation) AND (pain) AND (evidence OR guideline OR systematic).

The first 100 Google search results were screened and yielded no new studies. As Google search results are presented in order of relevance, we did not screen further.

Databases accessed

A highly sensitive search in the following health databases was undertaken and it replicated the previous search undertaken on the 5th November 2008

Table A2.2 Databases accessed

Database name	Dates covered	Date searched	Refs
CINAHL Plus	2008 - Current	26/05/2010	33
Cochrane Library	2008 - Current	27/05/2010	34
All EBM	2008 - 2nd Quarter 2010	26/05/2010	39
Embase	2008 - 2010 Week 20	26/05/2010	153
Medline	2008 - May Week 2 2010	26/05/2010	79
TOTAL			362

The following search was conducted in Medline and adapted for use in other databases.
No terms were included for comparison or outcomes to enable a broader search.

Table A2.3 Search undertaken in Medline

Database name	Strategy
Medline	1. pain.mp. or exp Pain/ 2. (persistent or chronic or long-term or refractory or intractable).mp.

	3. and/1-2 4. exp Denervation/ or denervation.mp. 5. neurotomy.mp. 6. ablation.mp. 7. (rhizotomy or rhizolysis).mp. 8. or/4-7 9. (radiofrequency or radio-frequency).mp. 10. 8 and 9 11. (facet and (coagulation or co-agulation)).mp. 12. 10 or 11 13. 3 and 12

Table A2.4 Website searches to identify relevant EBGs (only 2008 - 2010)

Search 1: Identification of relevant guidelines for Radiofrequency Denervation using specific guideline-related websites		
Guideline Service	**Results**	**Search**
National Institute of Clinical Studies. Clinical Practice Guidelines Portal http://www.clinicalguidelines.gov.au/	Clinical guidelines for best practice management of acute and chronic whiplash-associated disorders http://www.clinicalguidelines.gov.au/search.php?pageType=2&fldglrID=1280&	Web page reviewed: Search by condition. Pain
National Health and Medical Research Council (NHMRC) www.nhmrc.gov.au	Acute pain management: scientific evidence http://www.nhmrc.gov.au/publications/synopses/cp104syn.htm	Web page reviewed: Guidelines, health
National Institute for Health and Clinical Excellence UK (NICE) www.nice.org.uk	No guidelines identified	Web page reviewed: Find guidance, health topic, Injuries, accidents and wounds, Musculoskeletal, Surgical procedures
New Zealand Guideline Group (NZGG) www.nzgg.org.nz	No guidelines identified	Web page reviewed: Guidelines and Reports
Scottish Intercollegiate Guidelines Network (SIGN) www.sign.ac.uk	No guidelines identified	Web page reviewed: Guidelines
Joanna Briggs Institute www.joannabriggs.edu.au	No guidelines identified	Web page reviewed: Systematic reviews & best practice information (member access only)
Guidelines International Network www.g-i-n.net	No guidelines identified	Web page reviewed:: International Guideline Library (members only) Searched by keywords: radiofrequency, coagulation, denervation
Guidelines Advisory Committee www.gacguidelines.ca	No guidelines identified	Web page reviewed: List all topics and summaries
National Guideline Clearinghouse US (NGC) (1) **searched on 27/05/2010 –5 Results total** www.guidelines.gov	Low back - lumbar & thoracic (acute & chronic). Work Loss Data Institute - Public For Profit Organization. 2003 (revised 2008 Jun 10). 481 pages. NGC:006562 Neck and upper back (acute & chronic). Work Loss Data Institute - Public For Profit Organization. 2003 (revised 2008 May 7). 283 pages. NGC:006563 Hip & pelvis (acute & chronic). Work Loss Data Institute - Public For Profit Organization. 2006 (revised 2008 May 7). 163 pages. NGC:006560 Diagnosis and treatment of obstructive sleep apnea in adults. Institute for Clinical Systems Improvement - Private Nonprofit Organization. 2003 Apr (revised 2008 Jun). 55 pages. NGC:006582 Benign prostatic hyperplasia. Finnish Medical Society Duodecim - Professional Association. 2001 Apr 30 (revised 2008 Sep 27). Various pagings. NGC:006739	Searched by: **Keyword:** (radiofrequency OR coagulation) AND (denervation OR neurotomy OR ablation) AND pain
TRIP Database www.tripdatabase.com (1) **searched on 07/02/10 – 25 Results total** Limited to Guidelines: Aus. & NZ 1, Canada 6, UK 13, USA 2, Other 3	Neck pain - whiplash injury CKS (formerly PRODIGY) 2009	Searched by: **Keyword:** (radiofrequency OR coagulation) AND (denervation OR neurotomy OR ablation) AND pain
Australian Government Websites containing Guidelines		
Australian Government Department of Health and Ageing	No guidelines identified	Web page reviewed: Health Professionals – Treatments & Techniques –

www.health.gov.au		Guidelines
NSW Health www.health.nsw.gov.au	No guidelines identified	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	No guidelines identified	Web page reviewed: Resources – 'Reports, Guidelines and Article'
Other Accident Commissions		
Motor Accidents Authority NSW www.maa.nsw.gov.au/	http://www.maa.nsw.gov.au/default.aspx?MenuID=170	Web page reviewed: Publications & Reports – MAA Guidelines – Guides for Professionals
Accident Compensation Corporation www.acc.co.nz/index.htm	Radiofrequency (RF) neurotomy: Trigeminal nerve http://www.acc.co.nz/for-providers/clinical-best-practice/interventional-pain-management/interventions/body-map/WCM1_033797	Web page reviewed:: For Providers – Clinical Best Practice – Interventional pain management
WorkSafe VIC www.workcover.vic.gov.au	Musculoskeletal injuries http://www.worksafe.vic.gov.au/wps/wcm/connect/wsinternet/WorkSafe/Home/Safety+and+Prevention/Health+And+Safety+Topics/Musculoskeletal+Injuries/	Web page reviewed: Safety & Prevention; Health and Safety Topics
Work Cover NSW www.workcover.nsw.gov.au	http://www.workcover.nsw.gov.au/formspublications/Pages/default.aspx?Category=Injury+Management+and+Return-to-Work&SubCategory=Medical+practitioners	Web page reviewed: Forms and Publications Category: Medical practitioners
Work Cover WA www.workcover.wa.gov.au	http://www.workcover.wa.gov.au/Health+Providers/Overview/Default.htm	Web page reviewed: Health providers overview
Pain Websites		
British Pain Society http://www.britishpainsociety.org	No guidelines identified	Web page reviewed: Publications
Faculty of Pain Medicine – Australian New Zealand College of Anaesthetists http://www.anzca.edu.au/fpm/	PS45 : Statement on Patients' Rights to Pain Management and Associated Responsibilities – 2010 http://www.anzca.edu.au/fpm/resources/professional-documents	Web page reviewed:: Resources, Professional Documents
American Pain Society http://www.ampainsoc.org	Interventional Therapies, Surgery, and Interdisciplinary Rehabilitation for Low Back Pain: An Evidence-Based Clinical Practice Guideline From the American Pain Society http://www.ampainsoc.org/pub/cp_guidelines.htm	Web page reviewed: Publications, Clinical Practice Guidelines
The American Academy of Pain Medicine http://www.painmed.org/	No guidelines identified	Web page reviewed: Clinical Information, Clinical Guidelines
The Pain Association of Singapore http://www.pain.org.sg/	Not accessible on the day	Web page reviewed: Pain Guidelines and Management
European Society of Regional Anaesthesia and Pain Therapy http://www.esraeurope.org/	Guideline not dated	ESRA clinical practice guideline clearly linked from homepage toolbar
Search 2: Identification of relevant studies for Radiofrequency Denervation using Google		

Find web pages that have **all these words**	(radiofrequency OR coagulation) AND (denervation OR neurotomy OR ablation) AND (pain) AND (evidence OR guideline OR systematic)
Language	English
Date:	Past year
Results (27/05/2010) completed search:	About 149,000 results

Appraisal

Appraisal was undertaken in steps:

1. The most recent review (evidence-based guideline, 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 were appraised using standard criteria by a single reviewer in consultation with colleagues as required. Usually EBGs are appraised using the AGREE criteria (www.agreecollaboration.org), however, this instrument has some limitations, particularly in relation to appraisal of the systematic review methods used by the evidence-based guideline developers. Since we are most interested in the systematic review used to inform the evidence-based guideline, we used a systematic review framework when appraising EBGs. RCTs were also appraised using standard criteria by a single reviewer in consultation with colleagues as required. Details of quality appraisals are included in Appendix 5.

Data Extraction

Data on characteristics of the studies were extracted and summarised.

Consistency of findings

Where a current, good quality review was available, the findings were compared with those in the other available literature to identify any inconsistencies in the information provided.

APPENDIX 3: LIST OF INCLUDED STUDIES

1. ACC. Radiofrequency (RF) Neurotomy: Cervical Medial Branch. Considered Judgement Form. Accident Compensation Corporation, New Zealand. http://www.acc.co.nz/; 2006.
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APPENDIX 4: SUMMARY OF INCLUDED STUDIES

Summary of included studies by anatomical location

Table A4.1 summary of included cervical studies

1st author, year, title	Clinical indication	Study design	Conclusion/Recommendation	Recommendation category	Quality assessment results (risk of bias)
EVIDENCE BASED GUIDELINES					
American Society of Anesthesiologists (2010) Practice guidelines for chronic pain management: an updated report by the American Society of Anesthesiologists	"conventional radiofrequency ablation for patients with neck pain and no radiculopathy"	EBG	"The Task Force notes that other treatment modalities should be attempted before consideration of the use of ablative techniques…Conventional radiofrequency ablation may be performed for neck pain"	positive	Insufficient information to determine risk of bias Nb. Following critical appraisal it was determined that this study could not be considered an evidence-based guideline
Van Zundert (2009) Cervical radicular pain. Pain Practice	Cervical radicular pain	EBG	"Pulsed radiofrequency treatment adjacent to the cervical dorsal root ganglion is a recommended treatment for chronic cervical radicular pain (1B+). When its effect is insufficient or of short duration, conventional radiofrequency treatment is recommended (2B+)" EVIDENCE SCORES AND IMPLICATIONS: 1 B+ One RCT or more RCTs with methodologic weaknesses, demonstrate effectiveness. The benefits clearly outweigh risk and burdens - positive recommendation. 2 B+ One or more RCTs with methodologic weaknesses, demonstrate effectiveness. Benefits closely balanced with risk and burdens - positive recommendation	positive	Insufficient information to determine risk of bias
TRACsa (2008) Clinical guidelines for best practice management of acute and chronic whiplash associated disorders: Clinical resource guide	Chronic whiplash sufferers whose symptoms have been shown by diagnostic blocks to arise from the cervical joints	EBG	for chronic whiplash (>12 weeks) - treatments that may be undertaken provided there is ongoing evidence of benefit (and ***in addition*** to active exercise) include: Radiofrequency neurotomy (in carefully selected cases) GRADE B evidence "Radiofrequency neurotomy may be useful for chronic whiplash sufferers whose symptoms have been shown by diagnostic blocks to arise from the lower cervical joints [Grade B]" "[Grade B] Body of evidence can be trusted to guide practice in most situations"	positive	N/A Quality assessment not undertaken
WLDI (2008) Neck and upper back (acute and chronic). Official Disability	Chronic pain of cervical origin	EBG	"the evidence included in these guidelines is insufficient to make a recommendation about the effectiveness of radiotherapy denervation for chronic pain of cervical or lumbar origin"	Insufficient evidence	low risk of bias - most of the criteria have been fulfilled, and where criteria have not been fulfilled it is very unlikely the conclusions of the review would be affected.

1st author, year, title	Clinical indication	Study design	Conclusion/Recommendation	Recommendation category	Quality assessment results (risk of bias)
Guidelines					
ICSI (2008) Assessment and Management of Chronic Pain	Whiplash-related facet pain	EBG	" There is limited evidence for cervical RF neurotomy for whiplash-related facet pain (Lord, 1996 [A])"	insufficient evidence	N/A Quality assessment not undertaken
MAA NSW (2007) Guidelines for the management of acute whiplash-associated disorders (WAD)	Acute whiplash-associated disorders	EBG	the authors chose to review radiofrequency neurotomy as part of their list of treatment interventions but only found studies for RFD in *chronic* whiplash associated disorders (WAD); the focus of this guideline was *acute* WAD. Therefore, no evidence was found and no recommendations made about the use of RFD in acute WAD	N/A	N/A Quality assessment not undertaken
Boswell (2007) Interventional techniques: Evidence-based practice guidelines in the management of chronic spinal pain	Cervical facet joint pain	EBG	"Evidence for radiofrequency neurotomy of medial branch of cervical spine utilizing the techniques described by Lord et al (847), McDonald et al (862), and Barnsley (855) with multiple lesioning and strict criteria of 100% pain relief with diagnostic blocks, a tedious and time-consuming procedure as described by Bogduk (877), is strong for short- and long-term relief of cervical facet joint pain. Utilizing traditional radiofrequency neurotomy techniques as practiced in the United States in the cervical and lumbar region, the evidence for radiofrequency neurotomy of medial branches is strong for short-term and moderate for long-term relief. "	positive	N/A Quality assessment not undertaken
ACC (2006) Radiofrequency (RF) Neurotomy: Cervical Medial Branch. Considered Judgement Form	Persistent neck pain following motor vehicle accident	EBG	"There is medium quality evidence that radiofrequency neurotomy of the cervical medial branch is effective (for a median of nine months) in the treatment of adults with persistent neck pain following motor vehicle accident"..."This procedure should only be considered in a research setting with appropriate ethics approval by a practitioner who is appropriately trained and competent, preferably in a placebo controlled study." grade of recommendation B (supported by fair evidence)	positive	N/A Quality assessment not undertaken
HEALTH TECHNOLOGY ASSESSMENTS					
California Technology Assessment Forum (2007) Percutaneous Radiofrequency Neurotomy For Treatment Of Chronic Pain From The Upper Cervical (C2-3) Spine	Chronic neck pain Cervicogenic headache	HTA	"Because of the lack of sufficient number of rigorous trials and methodologic flaws in existing trials, it is not possible to sufficiently evaluate the efficacy and safety of percutaneous RF neurotomy in the treatment of cervicogenic headache or chronic neck pain."	insufficient evidence	N/A Quality assessment not undertaken
Greer (2005)	Facet-mediated neck	HTA	"With regard to percutaneous radiofrequency ablation for facet-mediated neck and	Positive	N/A

1st author, year, title	Clinical indication	Study design	Conclusion/Recommendation	Recommendation category	Quality assessment results (risk of bias)
Percutaneous Radiofrequency Ablation for Facet-Mediated Neck and Back Pain. Institute for Clinical Systems Improvement (ICSI)	pain		back pain, the ICSI Technology Assessment Committee concludes: 1. Percutaneous radiofrequency ablation is a safe procedure for patients who are correctly diagnosed with facet joint pain. 2. …percutaneous radiofrequency ablation may be an alternative for the patient who has failed an adequate trial of conservative therapy (including therapeutic exercise, activity modification, medical therapy, joint injections, and nerve blocks). (Conclusion Grade III based on Class A evidence; see Appendix A)"	(tentative)	Quality assessment not undertaken
Bassett (2001) Percutaneous radio-frequency neurotomy treatment of chronic cervical pain following whiplash injury: reviewing evidence and needs	Chronic neck pain following whiplash injury	HTA	"PRFN has been shown effective versus placebo in one RCT involving 24 very carefully selected patients with chronic neck pain following whiplash injury"	positive	N/A Quality assessment not undertaken
SYSTEMATIC REVIEWS					
Falco (2009) Systematic review of diagnostic utility and therapeutic effectiveness of cervical facet joint interventions	Chronic neck pain "patients were selected based on a positive response to controlled diagnostic blocks and 80% pain relief as the criterion standard"	SR	"the evidence is reasonably strong for… radiofrequency neurotomy... based on the radiofrequency neurotomy technique described by multiple investigators (61-63,110) the indicated evidence is Level II-1 to II-2 based on one randomized trial (61) and 3 observational studies (62,63,110)."	positive	Moderate risk of bias
Carragee (2008) Treatment of neck pain: injections and surgical interventions: results of the Bone and Joint Decade 2000-2010 Task Force on Neck Pain and Its Associated Disorders	neck pain alone or with radicular pain in the absence of serious pathologic disease Suspected facet zygopophysial pain	SR	"There were no scientifically admissible studies regarding radiofrequency neurotomy for suspected facet (zygopophysial) pain"	Insufficient evidence	N/A Quality assessment not undertaken
Cetas (2008) Destructive procedures for the treatment of	Non-malignant pain Cervical pain or	SR	no conclusions drawn	N/A	N/A Quality assessment not undertaken

1st author, year, title	Clinical indication	Study design	Conclusion/Recommendation	Recommendation category	Quality assessment results (risk of bias)
nonmalignant pain: a structured literature review	cervicogenic headache				
Kirpalani (2008) Cervical facet joint dysfunction: a review	Cervical facet joint dysfunction	SR	"...with only radiofrequency neurotomy showing evidence of effectively reducing pain from cervical facet joint dysfunction."..."RF neurotomy through a continuous or pulsed approach has been shown through limited studies to provide lasting pain relief from cervical facet joint dysfunction for several months."	Positive – limited evidence	N/A Quality assessment not undertaken
Malik (2008) Radiofrequency applications to dorsal root ganglia: A literature review. Anesthesiology	Cervicobrachial pain	SR	"With positive results in one high-quality RCT, there is level C or limited evidence of short-term efficacy of continuous RF-DRG in the treatment of cervicobrachial pain"	Positive – limited evidence	N/A Quality assessment not undertaken
Boswell (2007) A systematic review of therapeutic facet joint interventions in chronic spinal pain	Chronic cervical facet joint spinal pain	SR	"The evidence for pain relief with radiofrequency neurotomy of cervical...medial branch nerves is moderate for short- and long-term pain relief"	positive	N/A Quality assessment not undertaken
Jensen (2007) Strategies for prevention and management of musculoskeletal conditions. Neck pain.	Chronic neck pain	SR	"Radiofrequency denervation is effective in reducing pain in chronic neck pain." Ib+ (evidence from at least 1 RCT, positive)	positive	N/A Quality assessment not undertaken
Hoving (2006) Radiofrequency neurotomy as treatment for spinal joint pain: A systematic review of the literature	Unable to access	SR	Unable to access - no longer available on the internet	N/A	N/A Quality assessment not undertaken
Taylor (2006) Exploration of the evidence	Neuropathic pain	SR	"there was little evidence for the use of radiofrequency interventions or blocks"	Insufficient evidence	N/A Quality assessment not undertaken
Niemisto (2003) Radiofrequency denervation for neck	Chronic neck pain of zygapophyseal joint origin	SR	"The selected trials provide limited evidence that radiofrequency denervation offers short-term relief for chronic neck pain of zygapophyseal joint origin and for chronic cervicobrachial pain"..."In conclusion, short-term favourable outcomes can	positive	N/A Quality assessment not undertaken

1st author, year, title	Clinical indication	Study design	Conclusion/Recommendation	Recommendation category	Quality assessment results (risk of bias)
and back pain. A systematic review of randomized controlled trials	Chronic cervicobrachial pain		be expected from radiofrequency denervation among preselected individuals with chronic neck pain. However, radiofrequency denervation is a demanding, invasive method, liable to complications in unskilled hands, and requires special equipment and skilled staff"		
Manchikanti (2002) Medial branch neurotomy in management of chronic spinal pain: systematic review of the evidence	Chronic cervical spinal pain	SR	"the present review concludes that radiofrequency neurotomy of cervical, thoracic, or lumbosacral medial branches is an effective treatment for management of chronic spinal pain"	positive	N/A Quality assessment not undertaken
Geurts (2001) Efficacy of radiofrequency procedures for the treatment of spinal pain: a systematic review of randomized clinical trials	chronic cervical zygapophyseal joint pain after flexion-extension injury	SR	"...limited evidence exists for efficacy of RF neurotomy in chronic cervical zygapophyseal joint pain after flexion-extension injury."	Positive – limited evidence	N/A Quality assessment not undertaken
RANDOMISED CONTROLLED TRIALS					
Lord (1996) Percutaneous radio-frequency neurotomy for chronic cervical zygapophyseal-joint pain	patients with chronic cervical zygapophyseal-joint pain confirmed with double-blind, placebo-controlled local anesthesia	RCT	"In patients with chronic cervical zygapophyseal-joint pain confirmed with double-blind, placebo-controlled local anesthesia, percutaneous radio-frequency neurotomy with multiple lesions of target nerves can provide lasting relief."..."We found that radio-frequency neurotomy provided lasting, complete relief, but only in a moderate proportion of patients. Nevertheless, as shown in this study and previously,16 such relief can last for months to over a year, and if pain recurs the relief can usually be reinstated by repeating the procedure."	positive	**Limited evidence of benefit of radiofrequency denervation for relief of chronic neck pain.** The authors present a well conducted RCT, with low risk of bias, and with results suggesting the benefit of using radiofrequency denervation for relief of chronic neck pain in a moderate proportion of patients (7 out of 12 treated patients remained pain free at 27 weeks). However, in the absence of other, and large, well conducted trials, radiofrequency denervation should be recommended cautiously, bearing in mind the limitations in study methodology as well as generalisability described by the authors e.g. small sample size, specific diagnostic method, specific radiofrequency denervation technique. “Our results apply only to patients responsive to double-blind, placebo-controlled, diagnostic blocks whose treatment

1st author, year, title	Clinical indication	Study design	Conclusion/Recommendation	Recommendation category	Quality assessment results (risk of bias)
					involves multiple lesions of the target nerves. The results cannot be generalized to apply to patients whose pain is confirmed by less stringent criteria or who are treated with less exacting variants of the technique."
CONTROLLED TRIALS					
none					

Table A4.2 summary of included thoracic studies

1st author, year, title	Clinical indication	Study design	Conclusion/Recommendation	Recommendation category	Quality assessment results (risk of bias)
EVIDENCE BASED GUIDELINES					
none					
HEALTH TECHNOLOGY ASSESSMENTS					
none					
SYSTEMATIC REVIEWS					
Alturi (2008) Systematic review of diagnostic utility and therapeutic effectiveness of thoracic facet joint interventions	Upper back and mid back pain	SR	"The literature search revealed 34 studies for radiofrequency Neurotomy. Of these, 2 studies were identified which showed percutaneous facet denervation of medial branches. However, both of them failed to meet inclusion criteria, with low methodological quality… Based on the review of the included therapeutic studies described herein, no evidence synthesis is available for thoracic radiofrequency neurotomy."	Insufficient evidence	Low risk of bias - most of the criteria have been fulfilled, and where criteria have not been fulfilled it is very unlikely the conclusions of the review would be affected.
Boswell (2007). A systematic review of therapeutic facet joint interventions in chronic spinal pain	Chronic spinal pain	SR	"the evidence for radiofrequency neurotomy of medial branches is strong for short-term and moderate for long-term relief"	Insufficient evidence	N/A Quality assessment not undertaken
Hoving (2006) Radiofrequency neurotomy as treatment for spinal joint pain: A systematic review of the literature	Unable to access	SR	Unable to access - no longer available on the internet	N/A	N/A Quality assessment not undertaken
Machikanti (2002) Medial branch neurotomy in management of chronic spinal pain	Chronic spinal pain	SR	"The results of this systematic review provided strong evidence that radiofrequency denervation offers short-term relief and moderate evidence of long-term relief of pain with chronic thoracic pain."	Positive	N/A Quality assessment not undertaken
RANDOMISED CONTROLLED TRIALS					
none					
CONTROLLED TRIALS					
none					

Table A4.3 summary of included lumbar studies

1st author, year, title	Clinical indication	Study design	Conclusion/Recommendation	Recommendation category	Quality assessment results (risk of bias)
EVIDENCE BASED GUIDELINES					
American Society of Anesthesiologists (2010) Practice guidelines for chronic pain management: an updated report by the American Society of Anesthesiologists	Lumbar pain	EBG	"Conventional (*e.g.*, 80°C) or thermal (*e.g.*, 67°C) radiofrequency ablation of the medial branch nerves to the facet joint should be performed for low back (medial branch) pain when previous diagnostic or therapeutic injections of the joint or medial branch nerve have provided temporary relief." "Conventional or other thermal radiofrequency ablation of the dorsal root ganglion should not be routinely used for the treatment of lumbar radicular pain."	Positive – limited evidence	Insufficient information to determine risk of bias. Nb. Following critical appraisal it was determined that this study could not be considered an evidence-based guideline.
WLDI (2008) Official disability guidelines. Low back and Thoracic Guidelines (acute and chronic chapter).	Chronic low back and lumbar pain	EBG	"the evidence included in these guidelines is insufficient to make a recommendation about the effectiveness of radiotherapy denervation for chronic pain of lumbar origin"	Insufficient evidence	Low risk of bias - most of the criteria have been fulfilled, and where criteria have not been fulfilled it is very unlikely the conclusions of the review would be affected.
ICSI (2008) Assessment and Management of Chronic Pain	Chronic pain	EBG	"Invasive treatments including radiofrequency facet denervation and intradiscal radiofrequency lesioning have limited scientific evidence"	Insufficient evidence	N/A Quality assessment not undertaken
Airaksinen (2008) European guidelines for the management of chronic non-specific low back pain	Low back pain	EBG	"There is conflicting evidence that RF denervation of the facet joints is more successful than placebo for eliciting short-term or long-term improvements in pain or functional disability in mechanical chronic low back pain (level C). Proper selection of the patients (successful diagnostic blocks) and an optimal technique may be important to achieve better results. We cannot recommend RF facet denervation for patients with non-specific chronic low back pain."	Does not support use	N/A Quality assessment not undertaken
ACC (2006) Radiofrequency (RF) Neurotomy: lumbar medial branch considered judgment form	Low back pain	EBG	"The general use of radiofrequency neurotomy of the lumbar medial branch is not recommended for the treatment of adults with lower back pain. However, the procedure may be considered in the research setting."	Does not support use	N/A Quality assessment not undertaken
Boswell (2007) Interventional techniques: Evidence-based practice guidelines in the management of chronic spinal pain	Chronic Spinal Pain	EBG	The evidence for medial branch neurotomy is moderate."	Insufficient evidence	N/A Quality assessment not undertaken

1st author, year, title	Clinical indication	Study design	Conclusion/Recommendation	Recommendation category	Quality assessment results (risk of bias)
HEALTH TECHNOLOGY ASSESSMENTS					
Murtagh (2006) Radiofrequency neurotomy for lumbar pain	Lumbar pain	HTA	"Four systematic reviews of this procedure offer disparate conclusions. One small well designed observational study has shown positive results, but no equally rigorous randomized controlled trial has been conducted."	Insufficient evidence	N/A Quality assessment not undertaken
Greer (2005) Radiofrequency ablation for facet mediated neck and back pain	Lumbar pain	HTA	"Percutaneous Radiofrequency Ablation for Facet-Mediated Neck and Back Pain. The scientific evidence, to date, does not permit a conclusion to be reached regarding the efficacy of percutaneous radiofrequency ablation for *lumbar* facet joint pain."	Insufficient evidence	N/A Quality assessment not undertaken
SYSTEMATIC REVIEWS					
Chou (2009) Nonsurgical interventional therapies for low back pain	Low back pain	SR/EBG	"There is insufficient (poor) evidence from randomized trials (conflicting trials, sparse and lower quality data, or no randomized trials) to reliably evaluate radiofrequency denervation."	Insufficient evidence	Low risk of bias - most of the criteria have been fulfilled, and where criteria have not been fulfilled it is very unlikely the conclusions of the review would be affected.
Datta (2009) Systematic assessment of diagnostic accuracy and therapeutic utility of lumbar facet joint interventions	lumbar facet joint pain	SR	"Strong recommendation for radiofrequency neurotomy despite moderate to very low quality of evidence. This may change when higher quality evidence becomes available"	Positive	N/A Quality assessment not undertaken
Malik (2008) Radiofrequency Applications to Dorsal Root Ganglia	Spinal pain	SR	"Limited evidence against the use of radiofrequency application to the Dorsal Root Ganglia exists in the treatment of lumbar radicular pain... The mechanisms of action of continuous RF-DRG remain poorly understood."	Insufficient evidence	N/A Quality assessment not undertaken
Cetas (2008) Destructive procedures for the treatment of non-malignant pain: a structured literature	Non malignant pain	SR	"There is limited evidence supporting the efficacy of destructive techniques for the treatment of non-malignant chronic pain."	Insufficient evidence	N/A Quality assessment not undertaken
Hoving (2006) Radiofrequency neurotomy as treatment for spinal joint pain: A	Unable to access	SR	Unable to access - no longer available on the internet	Insufficient evidence	N/A Quality assessment not undertaken

1st author, year, title	Clinical indication	Study design	Conclusion/Recommendation	Recommendation category	Quality assessment results (risk of bias)
systematic review of the literature					
Van Tulder (2006) Outcome of invasive treatment modalities on back pain and sciatica: An evidence-based review.	Sciatica and chronic back pain	SR	"There is conflicting evidence for the effectiveness of radiofrequency denervation for lumbar facet joint pain."	Insufficient evidence	N/A Quality assessment not undertaken
Boswell (2007) A systematic review of therapeutic facet joint interventions in chronic spinal pain	Chronic spinal pain	SR	"the evidence for radiofrequency neurotomy of medial branches is strong for short-term and moderate for long-term relief"	Positive – limited evidence	N/A Quality assessment not undertaken
Hooten (2005) Radiofrequency neurotomy for low back pain: Evidence-based procedural guidelines.	Chronic low back pain	SR	"As a result of procedural limitations, the efficacy of RF neurotomy for lumbar zygapophysial joint pain remains undetermined despite three RCTs."	insufficient evidence	N/A Quality assessment not undertaken
Niemisto (2003) Radiofrequency denervation for neck and back pain: a systematic review with the framework of the Cochrane Collaboration Back Review Group.	Chronic back pain	SR	"The selected trials provide limited evidence that radiofrequency denervation offers conflicting evidence on the short-term effect of radiofrequency lesioning on pain and disability in chronic low-back pain of zygapophyseal joint origin"	insufficient evidence	N/A Quality assessment not undertaken
Slipman (2003) A critical review of the evidence for the use of zygapophysial injections and radiofrequency denervation in the treatment of low back pain	Chronic back pain	SR	"Current studies fail to give more than sparse evidence to support the use of interventional techniques in the treatment of lumbar zygapophysial joint–mediated low back pain."	Positive	N/A Quality assessment not undertaken
Manchikanti (2002) Medial Branch neurotomy	Chronic spinal pain	SR	"The results of this systematic review of 2 well-designed randomized trials, 4 prospective well-designed trials without randomization and 3 retrospective	Positive	N/A Quality assessment not undertaken

1st author, year, title	Clinical indication	Study design	Conclusion/Recommendation	Recommendation category	Quality assessment results (risk of bias)
in management of chronic spinal pain: Systematic review of the evidence			evaluations provided strong evidence that radiofrequency denervation offers short-term relief and moderate evidence of long-term relief of pain with chronic low back"		
Geurts (2001) Efficacy of radiofrequency procedures for the treatment of spinal pain: A systematic review of randomized clinical trials	Chronic spinal pain	SR	"We conclude that there is moderate evidence that RF lumbar facet denervation is more effective for chronic low back pain than placebo."	insufficient evidence	N/A Quality assessment not undertaken

Table A4.4 summary of included lumbar RCT (Nath, 2008)

Nath, S., C. A. Nath, et al. (2008). "Percutaneous lumbar zygapophysial (Facet) joint neurotomy using radiofrequency current, in the management of chronic low back pain: a randomized double-blind trial." Spine 33(12): 1291-1298.	
Design	RCT
Population characteristics	Adult patients with continuous low back pain of at least 2 years duration who had not responded to previous treatment.
Controlled facet joint blocks to select patients	Yes
Inclusion criteria	Patients diagnosed with lumbar zygapophysial joint pain with controlled local anesthetic blocks using Lidocaine or Bupivacaine.
Exclusion criteria	1/ patients with negative screening blocks 2/ patients with negative controlled blocks 3/ patients with prolonged response to blocks 4/ (pregnancy, coagulopathies, malignancy, infections, mental handicap, and psychiatric disorders; patients with a motor deficit or any other indication for surgical treatment; patients living too far away to be able to guarantee follow-up.)
Number of patients	N=40
Intervention	radiofrequency denervation 6 lesions of 60 second duration performed at a temperature of 85°C
Controls	sham procedure
Outcome	Primary: - global perception of improvement - relief of generalized pain, low back pain, and pain in the lower limb Secondary: - back movement - hip movement - quality of life variables (personal hygiene, walking, sitting, sleep, traveling, social life, standing, leisure, sex, work)
Pain measurement method used	visual analog scale (VAS) own subject assessment using a 6- point scale goniometer
Follow up period	6 months
Results (outcome of interest)	(Back pain) treatment group: baseline: 5.98 intervention: 3.88 pre/post diff: -2.1 control group: baseline: 4.38 intervention: 3.68 pre/post diff: -0.7
	difference treatment/placebo: -1.44 (95% CI: -3 to 0.17; p=0.08)
Authors' conclusion	"our study indicates that radiofrequency denervation is not a placebo and could be used in the treatment of carefully selected patients with chronic low back pain."
Recommendation category	supports use

Table A4.5 summary of included lumbar RCT (Tekin, 2007)

Tekin, I., H. Mirzai, G. Ok, K. Erbuyun and D. Vatansever (2007) A comparison of conventional and pulsed radiofrequency denervation in the treatment of chronic facet joint pain. Clinical Journal of Pain. 23(6): 524-529.	
Design	RCT
Population characteristics	Patients over 17 with continuous low back pain experienced for more than 6 months, with or without radiating into the upper leg, with focal tenderness over the facet joints, unresponsive to traditional conservative treatments.
Controlled facet joint blocks to select patients	No
Inclusion criteria	patients diagnosed with low back pain diagnosed with a single diagnostic medial branch procedure using 0.3 mL of lidocaine and who reported a VSA pain score reduction greater than 50%
Exclusion criteria	1/ subjects with less than 50% pain reduction 2/ patients with neurologic defects, indication for low back surgery or no radicular syndrome 3/ Prior RF treatment, coagulation disturbances, allergies to radiopaque contrast media or local anesthetics, malignancy, mental handicap or psychiatric condition precluding adequate communication, language problems, pregnancy
Number of patients	N=60
Intervention	1/ CRF lesion performed at 80°C for 90 seconds 2/two Hertz PRF waves applied for 4 min, with the end point being an electrode tip temperature 42°C
Controls	sham procedure
Outcome	low back pain and disability scores
Pain measurement method used	visual analog scale (VAS) and Oswestry Disability Index (ODI)
follow up period	12 months
Results (outcome of interest)	**CRF group** VSA score preprocedure: 6.5 ± 1.5 VSA score postprocedure: 2.3 ± 1.4 VSA score after 6 months: 2.3 ± 1.3 VSA score after 1 year: 2.4 ± 1.1 OSW score preprocedure: 39.2 ± 3.5 OSW score postprocedure: 25.6 ± 6.5 OSW score after 6 months: 25.1 ± 6.4 OSW score after 1 year: 28.0 ± 7.1 **Control group** VSA score preprocedure: 6.8 ± 1.6 VSA score postprocedure: 4.3 ± 1.0 VSA score after 6 months: 3.1 ± 0.8 VSA score after 1 year: 3.9 ± 1.2 OSW score preprocedure: 40.1 ± 2.8 OSW score postprocedure: 30.5 ± 5.7 OSW score after 6 months: 28.9 ± 5.7 OSW score after 1 year: 33.6 ± 5.7
Authors' conclusion	"our results show that VSA and ODI lower in CRF group than the control group at post procedure evaluation. The decrease was maintained at 6 months and 1 year... In conclusion, CRF is safe and useful intervention in the treatment of chronic facet joint pain with minimal complication rate."
Recommendation category	supports use

Table A4.6 summary of included lumbar RCT (Van Wijk, 2005)

Van Wijk, R. M. A. W., J. W. M. Geurts, H. J. Wynne, E. Hammink, E. Buskens, R. Lousberg, J. T. A. Knape and G. J. Groen (2005) Radiofrequency denervation of lumbar facet joints in the treatment of chronic low back pain: A randomized, double-blind, sham lesion-controlled trial. Clinical Journal of Pain 21(4): 335-344.	
Design	RCT
Population characteristics	Patients more than 17 years of age with continuous low back pain into the upper leg for more than 6 months with focal tenderness over the facet joints.
Controlled facet joint blocks to select patients	No
Inclusion criteria	Patients with no radicular syndrome and no indication for low back surgery. Patients who had at least 50% pain reduction on a standard visual scale (VSA) after 30 minutes
Exclusion criteria	1/patients with less than 50% pain reduction on a standard visual analog scale (VSA) 2/patients with prior RF treatment, coagulation disturbances, allergies for radiopaque contrast or local anesthetic, malignancy, mental handicap or psychiatric condition precluding adequate communication, language problems, and pregnancy.
number of patients	N=81
Intervention	RF lesion performed at 80°C for 60 seconds
Controls	sham procedure
Outcome	Primary: - median VSA low pain score (median value of 4 measurement during 2 weeks) Secondary: - median VAS leg pain score - physical activity - analgesics intake
Pain measurement method used	visual analog scale (VAS) SF-36
Follow up period	3 months follow up with full blinding
Results (outcome of interest)	VAS low back pain score Baseline: intervention: 5.8 (SD 1.8) control: 6.5 (SD 1.8) Mean change after 3 months: intervention: -2.1, p=0.0001 control: -1.6, p=0.0003
Authors' conclusion	"in VAS scores, no difference in effect was observed, although in both RF and control group, a comparable significant decrease in VAS was found."
Recommendation category	insufficient evidence

Table A4.7 summary of included lumbar RCT (Leclaire, 2001)

Leclaire, R., L. Fortin, R. Lambert, Y. M. Bergeron and M. Rossignol (2001) Radiofrequency facet joint denervation in the treatment of low back pain: A placebo-controlled clinical trial to assess efficacy. Spine 26(13): 1411-1416.		
Design	RCT	
Population characteristics	Patients aged 18 to 65 years, with low back pain of more than 3 months duration.	
Controlled facet joint blocks to select patients	No	
Inclusion criteria	Patients who had experienced significant relief of their low back pain for at least 24 hours in the week after intra-articular facet injections.	
Exclusion criteria	patients who had any known allergy to a local anesthetic, a blood coagulation disorder, a cardiac pace-maker, sciatic pain with a neurologic deficit, low back pain not related to a mechanical disorder (e.g., bone lesion, spondylitis), low back surgery, or concomitant medical illness likely to compromise ability to participate.	
Number of patients	N=70	
Intervention	RF lesion performed at 80°C for 90 seconds	
Controls	sham procedure	
Outcome	1/ disability scores (0-100) higher scores mean worst functional status 2/ pain score (0 no pain-100 worst pain possible)	
Pain measurement method used	1/Roland-Morris questionnaire score the Oswestry scale 2/visual analogue pain scale	
Follow up period	3 months	
Results (outcome of interest)	Neurotomy group (mean scores) **Baseline** RMQ: 59.2 (SD 18.2) Owestry scale: 38.3 (SD 14.7) VAS: 51.9 (SD 26.7) **4 weeks after treatment** RMQ: 44.5 change from baseline: 8.4 (SD 17.4) Owestry scale: 35.6 change from baseline: 2.7 (SD 12.4) VAS: 48.2 change from baseline: 3.6 (SD 24) **12 weeks after treatment** RMQ: 43.1 change from baseline: 9.8 (SD 19.5) Owestry scale: 33.6 change from baseline: 4.7 (SD 12.0) VAS: 52.3 change from baseline: -0.5 (SD 25)	Placebo group (mean scores) **Baseline** RMQ: 51.6 (SD 22.8) Owestry scale: 36.4 (SD 14.6) VAS: 51.5 (SD 20.8) **4 weeks after treatment** RMQ: 49.5 change from baseline: 2.2 (SD 14.7) Owestry scale: 34.4 change from baseline: 2.1 (SD 9.4) VAS: 52.1 change from baseline: -0.6 (SD 23.6) **12 weeks after treatment** RMQ: 44.4 change from baseline: 7.2 (SD 17) Owestry scale: 33.7 change from baseline: 2.7 (SD 9.1) VAS: 44.4 change from baseline: 7.2 (SD 27.3)
	treatment effect 4 weeks RMQ: 6.2 (-1.3to13.8) p=0.05 Owestry scale: 0.6 (-4.5to5.7) p>0.05 VAS: 4.2 (-6.9to15.4) p>0.05 **treatment effect 12 weeks** RMQ: 2.6 (-6.2to11.4) p>0.05 Owestry scale: 1.9 (-3.2to7.0) p>0.05 VAS: -7.6 (-20.3to5.1) p>0.05	
Authors' conclusion	"Although radiofrequency facet joint denervation may provide some short-term improvement in functional disability among patients with chronic low back pain, the efficacy of this treatment has not been established."	
Recommendation category	insufficient evidence	

Table A4.8 summary of included lumbar RCT (Van Kleef, 1999)

Van Kleef, M., G. A. M. Barendse, A. Kessels, H. M. Voets, W. E. J. Weber and S. De Lange (1999) Randomized trial of radiofrequency lumbar facet denervation for chronic low back pain. Spine 24(18): 1937-1942.	
Design	RCT
Population characteristics	Patients aged between 20 and 60 years, chronic low back pain of more than 12 months' duration, an initial mean visual analog scale (VAS) score of more than 4 or a VAS high score of more than 7, conservative therapy attempted without success and absence of any neurologic deficit by routine neurologic examination.
Controlled facet joint blocks to select patients	No
Inclusion criteria	Patients who had at least 50% pain relief, on a Likert scale, 30 minutes after the blocks were administered
Exclusion criteria	1/ patients with less than 50% pain relief 2/ excluded from the study were patients who had had previous back surgery and patients with a known specific cause of low back pain (i.e., signs of herniation, spondylolisthesis, spondylosis ankylopoetica, spinal stenosis, extensive multilevel spondylosis, malignancy, infection, or trauma). Patients with diabetes mellitus and patients with more than one pain syndrome were also excluded.
Number of patients	N=31
Intervention	RF lesion performed at 80°C for 60 seconds
Controls	sham procedure
Outcome	1/ mean VAS pain score (averaging 3 daily measurements for 4 days, ranging from 0 to 10cm) 2/ change in minimum (VAS-low) and maximum (VAS-high) scores over 4 days 3/ Global perceived effect score (ranging from much worse, -3; to 0, no change, to total pain relief, +3) 4/ physical impairment (ranging from 0, no impairment, to 7, maximum impairment) 5/ analgesic intake 6/ disability 7/quality of life
Pain measurement method used	1/ Visual analog scale 2/ Visual analog scale 4/ Waddell scale for low back pain and disorders assessment 5/ number of analgesic tablets per 4 days 6/Oswestry disability scale 7/ COOP/WONCA quality of life questionnaire
Follow up period	2 months
Results (outcome of interest)	**CFR group** Mean VAS score pretreatment: 5.2 (SD of 1.7) Mean VAS score posttreatment: 2.83 effect in treatment group: -2.37 High VAS scores pretreatment: 7.7 (SD of 1.5) High VAS scores posttreatment: 4.06 effect in treatment group: -3.64 Low VAS scores pretreatment: 2.9 (SD of 1.8) Low VAS scores posttreatment: 1.05 effect in treatment group: -1.85 OSW score pretreatment: mean OSW 31.0 (SD of 14.2) OSW score posttreatment: mean OSW 19.3 effect in treatment group: -11.07 **Sham group** VAS score pretreatment: mean VAS 5.2 (SD of 1.6) VAS score posttreatment: mean VAS 4.77 effect in sham treatment group: -0.43 High VAS scores pretreatment: 7.6 (SD of 1.7) High VAS scores posttreatment: 6.4 effect in treatment group: -1.02 Low VAS scores pretreatment: 3.0 (SD of 1.7) Low VAS scores posttreatment: 3.48 effect in treatment group: 0.48 OSW score pretreatment: mean OSW 38.0 (SD of 13.1) OSW score posttreatment: mean OSW 36.31 effect in sham treatment group: -1.69
Authors' conclusion	"Radiofrequency lumbar zygapophysial joint denervation results in a significant alleviation of pain and functional disability in a select group of patients with low back pain, both on a long term and a short term basis."
Recommendation category	supports use

Table A4.9 summary of included lumbar RCT (Gallagher, 1994)

Gallagher, J., P. L. Petriccione Di Vadi, J. R. Wedley, W. Hamann, P. Ryan, I. Chikanza, B. Kirkham, R. Price, M. S. Watson, R. Grahame and S. Wood (1994) Radiofrequency facet joint denervation in the treatment of low back pain: A prospective controlled double-blind study to assess its efficacy. Pain Clinic 7(3): 193-198.	
Design	RCT
Population characteristics	Adult patients aged between 25 and 55 years with low back pain for more than 3 months
Controlled facet joint blocks to select patients	No
Inclusion criteria	1/ patient who felt pain relief after injection of local anaesthetic into and around the appropriate painful joints. 2/patients with tenderness at palpation, more pain on extension than on flexion, pain on rotation of the spine, referred pain (above the knee), pain exacerbated by exercise and relieved by rest, pain exacerbated by sitting or standing, pain not exacerbated by coughing or sneezing, radiological evidence of facet joint degeneration or predisposing factors, such as loss of disk height or spondylolisthesis at the painful level.
Exclusion criteria	1/ patients who gained no relief from the injections 2/ previous back operations, neurological signs of nerve root compression in the lower limbs, patients with major mental illness or sever personality disorder, pending compensation claims, general ill health
Number of patients	N=41
Intervention	Radiofrequency lesion at 80^{o}C for 90 seconds
Controls	sham procedure
Outcome	Pain scores made using VAS and McGill Pain Questionnaire, measured before denervation, at 1 month and 6 months
Pain measurement method used	1/ Visual analog scale 2/ shortened form of McGill Pain Questionnaire
follow up period	6 months
Results (outcome of interest)	unclear No intention to treat analysis
Authors' conclusion	"this study demonstrates that radiofrequency facet joint denervation when compared with placebo, is beneficial in patients who respond positively to peri-articular injection with local anaesthetic."
Recommendation category	Supports use

Table A4.10 summary of included sacroiliac studies

1st author, year, title	Clinical indication	Study design	Conclusion/Recommendation	Recommendation category	Quality assessment results (risk of bias)
EVIDENCE BASED GUIDELINES					
American Society of Anesthesiologists Task Force on Chronic Pain Management (2010). Practice guidelines for chronic pain management:	Non malignant chronic pain and pain related problems.	EBG	"Water-cooled radiofrequency ablation may be used for chronic sacroiliac joint pain"	Supports use	insufficient evidence to permit judgment
HEALTH TECHNOLOGY ASSESSMENTS					
none					
SYSTEMATIC REVIEWS					
Rupert (2009). Evaluation of sacroiliac joint interventions: A systematic appraisal of the literature.	Sacroiliac joint pain	SR	"This systematic review provides limited evidence for radiofrequency neurotomy of sacroiliac joint nerve supply. Cautious approach must be utilized for therapeutic management with intraarticular radiofrequency neurotomy based on individual patient circumstances and the clinician's experience and technical capabilities."	insufficient evidence	N/A
Hansen (2007). Sacroiliac joint interventions: A systematic review.	sacroiliac joint pain	SR	"This systematic review showed limited evidence for radiofrequency neurotomy in managing chronic sacroiliac joint pain."	insufficient evidence	N/A
Boswell (2007). A systematic review of therapeutic facet joint interventions in chronic spinal pain **Hoving (2006).** Radiofrequency neurotomy as treatment for spinal joint pain: A systematic review of the literature.	Chronic spinal pain	SR SR	"the evidence for radiofrequency neurotomy of medial branches is strong for short-term and moderate for long-term relief" "This systematic review found that there is no consistent evidence from either multiple (large) RCTs or systematic reviews that RF neurotomy is efficacious in the treatment of spinal joint pain RCTs need to be conducted with larger sample sizes, (patient) relevant outcomes and adequate assessment of side-effects, which can be serious."	insufficient evidence	N/A
McKenzie-Brown (2005). A systematic review of sacroiliac joint interventions.	Chronic sacroiliac joint pain	SR	"Based on the available literature, which consisted of 3 retrospective evaluations with small numbers of patients, the evidence for radiofrequency neurotomy in managing chronic sacroiliac joint pain was limited."	insufficient evidence	N/A
RANDOMISED CONTROLLED TRIALS					
Cohen (2008). Randomized placebo-controlled study evaluating lateral branch radiofrequency denervation for sacroiliac joint pain.	Sacroiliac joint pain	RCT	"L4 and L5 primary dorsal rami and S1–S3 lateral branch radiofrequency denervation may provide intermediate-term pain relief and functional benefit in selected patients with suspected sacroiliac joint pain. Larger studies are needed to confirm these results and to determine the optimal candidates and treatment parameters for this poorly understood disorder."	Supports use	N/A

1st author, year, title	Clinical indication	Study design	Conclusion/Recommendation	Recommendation category	Quality assessment results (risk of bias)
CONTROLLED TRIALS					
none					

APPENDIX 5: APPRAISAL TABLES

Table A5.1 Critical appraisal table (American Society of Anesthesiologists, 2010)

CERVICAL, LUMBAR & SACROILIAC Study: Practice Guidelines for Chronic Pain Management: An Updated Report by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine*. Anesthesiology. 2010;112(4):810-33	
Description of study: Evidence-Based Guideline – based on systematic review of level I-IV evidence.	
Patient/population	People with chronic non-cancer pain
N	Cervical: RCT (n=24) (Category A3 evidence – supportive literature) and other observational studies (insufficient information to count number of participants) Lumbar: meta-analysis of 5 RCTs for low back pain (Category A1 evidence – supportive literature) and RCT (n=83) for lumbar radicular pain (Category C2 evidence – equivocal literature) and other observational studies (insufficient information to count number of participants) Sacroiliac: RCT (n=28) (Category A3 evidence – supportive literature) and other observational studies (insufficient information to count number of participants) **Please note these participant and study numbers only represent those investigating radiofrequency denervation. Other studies, not addressing radiofrequency Denervation were also included in this guideline but are not reported or counted here.**
Setting	These Guidelines are intended for use by anaesthesiologists and other physicians serving as pain medicine specialists. The Guidelines recognize that all anesthesiologists or other physicians may not have access to the same knowledge base, skills, or range of modalities. However, aspects of the Guidelines may be helpful to anesthesiologists or other physicians who manage patients with chronic pain in a variety of practice settings. They may also serve as a resource for other physicians, nurses, and healthcare providers (*e.g.*, rehabilitation therapists, psychologists, and counselors) engaged in the care of patients with chronic pain. They are not intended to provide treatment algorithms for specific pain syndromes.
Intervention/indicator	Cervical: conventional radiofrequency ablation Lumbar: conventional or thermal radiofrequency ablation Sacroiliac: water-cooled radiofrequency ablation (among other therapeutic interventions)
Comparison/control	Cervical: not specified Lumbar: sham control Sacroiliac: sham control
Outcomes	Pain (cervical, lumbar or sacroiliac as relevant to each study)

Inclusion Criteria	"The interventions listed below were examined to assess their impact on a variety of outcomes related to chronic noncancer pain.#... III. Single Modality Interventions Ablative techniques: Chemical Denervation; Cryoneurolysis or cryoablation; Thermal intradiscal procedures (intervertebral disc annuloplasty [IDET], transdiscal biaculoplasty); Conventional or thermal radiofrequency ablation (facet joint, sacroiliac joint, dorsal root ganglion)..."
Exclusion Criteria	"After a review of the articles, 1550 studies did not provide direct evidence and were subsequently eliminated. A total of 696 articles contained direct linkage-related evidence."

Study Validity.		
Is it clear that there were no conflicts of interest in the writing or funding of this review?	Not reported	
Does the review have a clearly- focused question?	Partial	There is a general question implied in the 'focus' of the guidelines "These Guidelines focus on the knowledge base, skills, and range of interventions that are the essential elements of effective management of chronic pain and pain-related problems. The Guidelines recognize that the management of chronic pain occurs within the broader context of health care, including psychosocial function and quality of life. These Guidelines apply to patients with chronic noncancer neuropathic, somatic (e.g., myofascial), or visceral pain syndromes. The Guidelines do not apply to patients with acute pain from an injury or postoperative recovery, cancer pain, degenerative major joint disease pain, headache syndromes (e.g., migraine and cluster), temporomandibular joint syndrome, or trigeminal or other neuralgias of the head or face. In addition, the Guidelines do not apply to pediatric patients and do not address the administration of intravenous drugs or surgical interventions other than implanted intrathecal drug delivery systems and nerve stimulators." In the summary of evidence (p814) results studies upon which recommendations are based are reported in terms of the population, intervention, comparator and outcomes
Is a systematic review the appropriate method to answer the question?	Yes	
Does the review have specified inclusion/exclusion criteria?	Partial	A comprehensive list of interventions that were "examined to assess their impact on a variety of outcomes related to chronic noncancer pain" can be found in Appendix 2 (p822) "These Guidelines apply to patients with chronic noncancer neuropathic, somatic (*e.g.*, myofascial), or visceral pain syndromes. The Guidelines do not apply to patients with acute pain from an injury or postoperative recovery, cancer pain, degenerative major joint disease pain, headache syndromes (*e.g.*, migraine and cluster), temporomandibular joint syndrome, or trigeminal or other neuralgias of the head or face. In addition, the Guidelines do not apply to pediatric patients and do not address the administration of intravenous drugs or surgical interventions other than implanted intrathecal drug delivery systems and nerve stimulators. "The authors were looking for "evidence linkages or statements regarding potential relationships between clinical interventions and outcomes"

If there were specified inclusion/ exclusion criteria, were these appropriate?	Yes	
Does the review document a comprehensive search strategy?	Partial	Details of the search include a list of interventions examined in the guideline, followed by the statement "For the literature review, potentially relevant clinical studies were identified through electronic and manual searches of the literature. The electronic and manual searches covered a 56-yr period from 1944 to 2009." (Appendix2, p822) Actual search strategies used were not specified. There was no indication of the databases searched, if there was follow-up from reference lists or if the reviewers searched for unpublished studies. The authors were contacted to determine the search strategies used, but the authors no longer had a record of this information.
Were reviewers blind to authors, institutions and affiliations?	Not reported	
Were 2 or more independent reviewers used for: **1. application of inclusion criteria to assess eligibility of studies?**	Yes	"Interobserver agreement among Task Force members and two methodologists was established by interrater reliability testing. Agreement levels using a kappa (*k*) statistic for two-rater agreement pairs were as follows: (1) type of study design, *k* = 0.63– 0.88; (2) type of analysis, *k* = 0.87; (3) **evidence linkage assignment**, *k* = 0.82–1.00; and (4) **literature inclusion for database**, *k* = 0.83– 1.00. Three-rater chance-corrected agreement values were (1) study design, Sav = 0.72, Var (Sav) = 0.008; (2) type of analysis, Sav = 0.87, Var (Sav) = 0.005; (3) **linkage assignment**, Sav = 0.88, Var (Sav) = 0.003; (4) **literature database inclusion**, Sav = 0.88, Var (Sav) = 0.018. These values represent moderate to high levels of agreement." (Appendix 2 p823) Unclear if this was done for all studies or a sample. Unclear if this was done just for studies included in the meta-analyses.
2. extraction of data from study reports?	Yes	"Interobserver agreement among Task Force members and two methodologists was established by interrater reliability testing. Agreement levels using a kappa (*k*) statistic for two-rater agreement pairs were as follows: (1) **type of study design**, *k* = 0.63– 0.88; (2) **type of analysis**, *k* = 0.87; (3) **evidence linkage assignment**, *k* = 0.82–1.00; and (4) literature inclusion for database, *k* = 0.83– 1.00. Three-rater chance-corrected agreement values were (1) **study design**, Sav = 0.72, Var (Sav) = 0.008; (2) **type of analysis**, Sav = 0.87, Var (Sav) = 0.005; (3) **linkage assignment**, Sav = 0.88, Var (Sav) = 0.003; (4) literature database inclusion, Sav = 0.88, Var (Sav) = 0.018. These values represent moderate to high levels of agreement." (Appendix 2 p823) Unclear if this was done for all studies or a sample. Unclear if this was done just for studies included in the meta-analyses.
3. appraisal of study quality?	Not reported	
Were the strengths and limitations of included studies and potential impact on the results discussed?	Not reported	

Was the validity of included trials appraised using appropriate criteria?	Not reported	
Is there a summary of the results of individual studies?	Partial	"Study findings from published scientific literature were aggregated and are reported in summary form by evidence category, as described below. All literature (e.g., randomized controlled trials, observational studies, and case reports) relevant to each topic was considered when evaluating the findings. However, for reporting purposes in this document, only the highest level of evidence (i.e., levels 1, 2, or 3 identified below) within each category (i.e., A, B, or C) is included in the summary." General summary results reported for outcomes – i.e. "lower pain scores" without details of actual scores or differences between scores
If meta-analyses were conducted, was it reasonable to do so?	Partial	Not enough information to answer yes or no. The authors did not provide details on the studies included in the meta-analysis. "Literature pertaining to eight evidence linkages contained enough studies with well-defined experimental designs and statistical information sufficient for meta-analyses." (Appendix 2, p822)
If meta-analyses were conducted, was it done appropriately?	Yes	"General variance-based effect-size estimates or combined probability tests were obtained for continuous outcome measures, and Mantel-Haenszel odds-ratios were obtained for dichotomous outcome measures. Two combined probability tests were used as follows: (1) the Fisher combined test, producing chi-square values based on logarithmic transformations of the reported *P* values from the independent studies, and (2) the Stouffer combined test, providing weighted representation of the studies by weighting each of the standard normal deviates by the size of the sample. An odds ratio procedure based on the Mantel-Haenszel method for combining study results using 2 X 2 tables was used with outcome frequency information. An acceptable significance level was set at $P< 0.01$ (one tailed). Tests for heterogeneity of the independent studies were conducted to ensure consistency among the study results. Der-Simonian-Laird random-effects odds ratios were obtained when significant heterogeneity was found ($P <0.01$). To control for potential publishing bias, a "fail-safe n" value was calculated. No search for unpublished studies was conducted, and no reliability tests for locating research results were done."
Other		
What is the overall risk of bias?	Insufficient information	Insufficient information – not enough information provided on methodological quality to be able to determine risk of bias. This rating is mainly due to the lack of documentation about the search strategy used. Without this information it is impossible to tell if the authors searched appropriately and comprehensively enough to find all of the relevant studies. As the recommendations of the guideline are based on the studies found, this would have a direct impact on the findings of the review.

Results.

Evidence

Cervical: "A randomized controlled trial of conventional radiofrequency ablation for patients with neck pain and no radiculopathy reports pain relief for up to 6 months after the procedure (*Category A3 evidence*)...Consultants, ASA members, and ASRA members strongly agree that conventional (*e.g.*, 80°C) or thermal (*e.g.*, 67°C) radiofrequency ablation of the medial branch nerves to the facet joint should be performed for neck or low back (medial branch) pain"

Table 1. Meta-analysis Summary

Evidence Linkages	N	Fisher χ^2	*P* Values	Weighted Stouffer Zc	*P* Values	Effect Size	Odds Ratio	Confidence Interval	Heterogeneity Significance	Heterogeneity Effect Size
Ablative techniques: RF ablation vs. sham controls										
Pain scores at 2–6 mo follow-up	5	39.82	0.001	−4.02	0.001	−0.30			NS	NS

Lumbar:
"Meta-analytic findings from randomized controlled trials comparing conventional (*e.g.*, 80°C) or thermal (*e.g.*, 67°C) radiofrequency ablation of medial branches with sham controls report lower pain scores for assessment periods of 2–6 months after the procedure for patients with low back pain (*Category A1 evidence*)...
One randomized controlled trial reports no differences in lumbar radicular pain when thermal radiofrequency ablation of the dorsal root ganglion is compared with sham control (*Category C2 evidence*)...Consultants, ASA members, and ASRA members strongly agree that conventional (*e.g.*, 80°C) or thermal (*e.g.*, 67°C) radiofrequency ablation of the medial branch nerves to the facet joint should be performed for neck or low back (medial branch) pain...Consultants disagree and ASA members and ASRA members are equivocal with regard to whether conventional or thermal radiofrequency ablation of the dorsal root ganglion should be used for the treatment of lumbar radicular pain."

Sacroiliac: "One randomized controlled trial comparing water-cooled radiofrequency with sham control for chronic sacroiliac joint pain reports lower pain scores in the radiofrequency ablation group for up to 3 months (*Category A3 evidence*)...Consultants, ASA members, and ASRA members...are equivocal as to whether water-cooled radiofrequency ablation should be used for chronic sacroiliac joint pain."

Author's Conclusions.

Guideline recommendation:
"The Task Force notes that other treatment modalities should be attempted before consideration of the use of ablative techniques"
Cervical: "Conventional radiofrequency ablation may be performed for neck pain"
Lumbar: "Conventional (*e.g.*, 80°C) or thermal (*e.g.*, 67°C) radiofrequency ablation of the medial branch nerves to the facet joint should be performed for low back (medial branch) pain when previous diagnostic or therapeutic injections of the joint or medial branch nerve have provided temporary relief...Conventional or thermal radiofrequency ablation of the dorsal root ganglion should not be routinely used for the treatment of lumbar radicular pain"
Sacroiliac: "water-cooled radiofrequency ablation may be used for chronic sacroiliac joint pain"

Our Comments/Summary.

We are unable to draw conclusions on the effectiveness of RFD for chronic cervical, lumbar or sacroiliac joint pain as there is insufficient information provided by the authors to determine the overall risk of bias of this study. This is due to the fact that the authors were unable to give us information relating to the search strategies that they used. This makes us unable to determine the risk of bias in the results as we cannot be sure that the results have been based on all of the available literature.

Table A5.2 Critical appraisal table (Van Zundert, 2009)

CERVICAL **Study:** Van Zundert J, Huntoon M, Patijn J, Lataster A, Mekhail N, van Kleef M. 4. Cervical radicular pain. Pain Pract. (2009) Jan-Feb;10(1):1-17.		
Description of study: Evidence-Based Guideline (Systematic review of RCTs).		
Patient/population	Patients with cervical radicular pain	
N	2 RCTs (n=20, n=61) Please note, there were other studies included in this guideline, the ones outlined above relate specifically to recommendations about the use of radiofrequency denervation. **Please note all these studies may not have assessed our outcomes of interest.**	
Setting	Not stated	
Intervention/indicator	**Reference**	**Intervention**
	Slappendel 1997	RFD at 67 degrees C
	Van Kleef 1996	RFD at 67 degrees C to dorsal root ganglion
Comparison/control	**Reference**	**Comparison**
	Slappendel 1997	RFD at 40 degrees C
	Van Kleef 1996	Sham procedure
Outcomes	Efficacy (Pain relief) and complications	
Inclusion Criteria	Only articles published in peer-reviewed journals are included	
Exclusion Criteria	None mentioned	
Study Validity.		
Is it clear that there were no conflicts of interest in the writing or funding of this review?	Not reported	
Does the review have a clearly- focused question?	Partial	*The question is not phrased as a question, from different parts of the paper it appears that:* *population - patients with cervical radicular pain,* *intervention – both pulsed and conventional RFD* *outcomes considered – pain relief, complications*

Is a systematic review the appropriate method to answer the question?	Yes	
Does the review have specified inclusion/exclusion criteria?	No	*The only inclusion/exclusion criteria identified was:* "Only articles published in peer-reviewed journals are included"
If there were specified inclusion/ exclusion criteria, were these appropriate?	N/A	*Not enough information given about other inclusion/exclusion criteria to determine this*
Does the review document a comprehensive search strategy?	No	No details are provided about the search
Were reviewers blind to authors, institutions and affiliations?	Not reported	
Were 2 or more independent reviewers used for: **4. application of inclusion criteria to assess eligibility of studies?**	Not reported	
5. extraction of data from study reports?	Not reported	
6. appraisal of study quality?	Not reported	
Were the strengths and limitations of included studies and potential impact on the results discussed?	Not reported	
Was the validity of included trials appraised using appropriate criteria?	Not reported	
Is there a summary of the results of individual studies?	No	
If meta-analyses were conducted, was it reasonable to do so?	N/A	
If meta-analyses were conducted, was it done appropriately?	N/A	

Other		
What is the overall risk of bias?	Insufficient information	*Insufficient information – not enough information provided on methodological quality to be able to determine risk of bias.*

Results.

Table 5. Evidence for The Treatment Options For Cervical Radicular Pain

Technique	Score
Interlaminar corticosteroid administration	2B+
Transforaminal corticosteroid administration	2B–
Radiofrequency treatment adjacent to the dorsal root ganglion (DRG)	2B+
Pulsed radiofrequency treatment adjacent to the DRG	1B+*
Spinal cord stimulation	0

* The score 1B+ is established according to the methodology described in the editorial[2]. The authors want to stress the fact that more studies are needed to continue supporting this score.

"Radiofrequency Treatment: Efficacy. The efficacy of radiofrequency (RF) treatment adjacent to the dorsal root ganglion (DRG) was reported in two randomized clinical studies.59,60

The first study compared RF adjacent to the cervical DRG with a sham intervention. In the actively treated group, 8 weeks postintervention the Number Needed to Treat, i.e., the number of patients that need to be treated in order to have at least one patient who has at least a 50% reduction in pain, was 1.4.59

The second study compared RF with an electrode tip temperature of 40°C with RF at 67°C.60 At 6 weeks and at 3 months after treatment there was a significant decrease in the visual analog scale pain score in both groups. There was no significant difference in outcome between the two groups.

Radiofrequency Treatment: Complications. In the above-mentioned studies, transient neuritis and/or a burning sensation in the treated spinal nerve were reported. Additionally, a slight loss of muscular strength in the hand and arm of the treated side was reported."

Author's Conclusions.

Pulsed radiofrequency treatment adjacent to the cervical dorsal root ganglion is a recommended treatment for chronic cervical radicular pain (1B+). When its effect is insufficient or of short duration, conventional radiofrequency treatment is recommended (2B+).

Our Comments/Summary.

There is very little information in this paper in regard to methods. There is a separate 'methods' publication that covers a suite of guidelines (van Kleef M, Mekhail N, van Zundert J. Evidence-based guidelines for interventional pain medicine according to clinical diagnoses. Pain Pract. 2009 Jul-Aug;9(4):247-51.), but there is very little information on the specific methodology used in the development of this guideline.

There is insufficient information to assess the quality of this paper and to determine the risk of bias

Table A5.3 Critical appraisal table (Falco, 2009)

CERVICAL **Study**: Falco FJ, Erhart S, Wargo BW, Bryce DA, Atluri S, Datta S, et al. Systematic review of diagnostic utility and therapeutic effectiveness of cervical facet joint interventions. Pain Physician. 2009 Mar-Apr;12(2):323-44.		
Description of study: Systematic review of 1 RCT and observational studies		
Patient/population	Patients with cervical facet joint pain	
N	1 RCT (n=24), and 4 observational studies. *Please note all these studies may not have assessed our outcomes of interest.*	
Setting	Not stated	
Intervention/indicator	Radiofrequency neurotomy. *The authors also included diagnostic accuracy studies, however, these are not relevant to this report*	
Comparison/control	Sham for Lord 2001 RCT, no comparator for other included studies	
Outcomes	"For therapeutic interventions, the primary outcome measure was pain relief (short-term relief up to 6 months and long-term relief greater than 6 months) with secondary outcome measures of improvement in functional status, psychological status, return to work, and reduction in opioid intake."	
Inclusion Criteria	"Studies had to include evidence of the use of controlled diagnostic cervical facet joint injections or nerve blocks with 80% pain relief to be included in this systematic review. Three types of therapeutic interventions for facet joint pain were included in this study: intraarticular facet joint interventions, medial branch blocks, and medial branch neurotomy. All studies included were determined by outcome evaluations with at least a 6 month follow-up period and the use of appropriate statistical analysis."	
Exclusion Criteria	"The following studies were excluded from the review: essays, reviews, letters, editorials, abstracts, surveys, learning modules, and animal or cadaveric studies."	
Study Validity.		
Is it clear that there were no conflicts of interest in the writing or funding of this review?	No	The following statements are included in the study "conflict of interest: none" "If there was a conflict of interest with the reviewed manuscripts with authorship or any other type of conflict, the involved authors did not review the manuscripts for quality assessment, clinical relevance, evidence synthesis, or grading of evidence" However, there is still a *potential* conflict of interest as it was not reported whether this procedure was followed for determining eligibility for inclusion of studies in the review, and it was not reported whether the reviewers were blind to authors of articles that they were reviewing, meaning that even though the authors were not assessing their own papers, they were potentially assessing papers written by their colleagues, which could impact the results.
Does the review have a clearly- focused question?	Yes	*Clearly -focused question, but not presented as a sentence – elements of the question found in different places (i.e. population, outcomes)*
Is a systematic review the appropriate method to answer the question?	Yes	

Does the review have specified inclusion/exclusion criteria?	Yes	"Studies had to include evidence of the use of controlled diagnostic cervical facet joint injections or nerve blocks with 80% pain relief to be included in this systematic review. Three types of therapeutic interventions for facet joint pain were included in this study: intraarticular facet joint interventions, medial branch blocks, and medial branch neurotomy. All studies included were determined by outcome evaluations with at least a 6 month follow-up period and the use of appropriate statistical analysis." In addition each study had to score at least 50/100 for methodologic quality assessment to be included in the review "If there were 4 randomized trials evaluating any one of the techniques — namely intraarticular injections, medial branch blocks, or radiofrequency neurotomy, observational studies were not included in the methodologic quality assessment as well as the evidence synthesis" Only English-language studies were included The authors state that one study was excluded because it was "specific for third occipital nerve neurotomy with a specialized technique not applicable to the general population in the United States"
If there were specified inclusion/ exclusion criteria, were these appropriate?	Partial	It is not made explicit why the authors decided to exclude observational studies from quality assessment where there were 4 RCTs evaluating a technique. This and the decision to exclude a study due to lack of applicability of the technique used to the United States were not listed among the exclusion criteria, and do not seem to have been decided on apriori
Does the review document a comprehensive search strategy?	Partial	*Personal correspondence: "Since the literature is low for this topic just basic search strategies were used. An individual search was done in each database using a combination of the terms you mentioned.* *Examples:* *diagnostic cervical facet joint injections; cervical intraarticular facet joint blocks; cervical medial branch blocks; cervical radiofrequency neurotomy…etc* *cervical facet joints and therapies; cervical facet joints and treatments; cervical facet joints and diagnosis…etc* *A citation search was also performed on the major papers to find additional articles."*
Were reviewers blind to authors, institutions and affiliations?	No	*This could be an issue as the authors are known to each other*
Were 2 or more independent reviewers used for: **7. application of inclusion criteria to assess eligibility of studies?**	Yes	*Two authors, but it is unclear if it was done independently*
8. extraction of data from study reports?	Not reported	
9. appraisal of study quality?	Yes	

Were the strengths and limitations of included studies and potential impact on the results discussed?	Partial	*Strengths and limitations discussed, but only minimal discussion of potential impact on results* *There was limited discussion of the weaknesses of a study of which the first author is also an author of the systematic review*
Was the validity of included trials appraised using appropriate criteria?	Yes	
Is there a summary of the results of individual studies?	Yes	
If meta-analyses were conducted, was it reasonable to do so?	N/A	
If meta-analyses were conducted, was it done appropriately?	N/A	
Other		
What is the overall risk of bias?	Moderate	Moderate - Some of the criteria have been fulfilled and those criteria that have not been fulfilled may affect the conclusions of the study.

Results.

The literature search revealed 22 studies of radiofrequency neurotomy. Of these, one randomized trial and 4 observational studies met the inclusion criteria for methodologic quality assessment and also for evidence synthesis.

... Results of medial branch neurotomy in the cervical spine are illustrated in Table 9. All studies had a methodological quality of ≥ 50 of 100 points. The included studies showed positive short-term and long-term results.

Govind et al's study (121) was not included in Table 9 as this was specific for third occipital nerve neurotomy with a specialized technique not applicable to the general population in the United States.

Table 9. *Published results of studies of cervical medial branch neurotomy*

Study	***Study Characteristics***	***Methodological Quality Score(s)***	***Number of patients***	***Pain relief (months)***		***Results***	
				6 mos.	***12 mos.***	***Short term relief ≤ 6 mos***	***Long term relief >6 mos***
Lord et al (61)	RA,DB	67	24	1 of sham 7 of active	58% in active treatment group	P	P
Sapir and Gorup (62)	O	87	46	NA	Mean VAS change 4.6 ± 1.8	P	P
McDonald et al (63)	O	65	28	NA	71%	P	P
Barnsley (110)	O	54	35	NA	74%	P	P

RA = randomized; DB = double blind; O = Observational; NA = not available; VAS = visual analog scale; P = positive

Level of Evidence
The indicated level of evidence for radiofrequency neurotomy is Level II-1 to II-2 based on one randomized trial (61), and 3 (62,63,105) observational studies. However, the evidence is based on arriving at the diagnosis with at least 80% pain relief with controlled diagnostic blocks of either placebo or comparative local anesthetic and utilizing at least 2 lesions at each level based on the descriptions of Lord et al (61), Barnsley et al (110), Sapir and Gorup (62), and McDonald et al (63).
Recommendation
The systemic review found that according to Guyatt et al's criteria (104), the recommendation is 1B or C/strong for radiofrequency neurotomy.

The review also reported on outcomes for diagnostic facet joint nerve blocks, cervical intraarticular facet joint injections and cervical medial branch blocks, which was not part of our question

Author's Conclusions.

"Results for cervical facet joint radiofrequency neurotomy were also positive for short- and long-term pain relief for chronic cervical facet joint neck pain"

Our Comments/Summary.

This study presents a moderate risk of bias due to potential conflicts of interest from review authors assessing their colleagues' papers for inclusion and quality appraisal, and exclusion criteria that may have not been developed apriori (such as the exclusion of observational studies where 4 RCTs exist, and the exclusion of a study due to the applicability of the technique used to the US. Therefore, **this review should not be used to make recommendations on the efficacy of RFD for cervical joint pain**

Table A5.4 Critical appraisal table (Lord, 1996)

CERVICAL
Study: Lord, S. M., L. Barnsley, B. J. Wallis, G. J. McDonald and N. Bogduk (1996). "Percutaneous radio-frequency neurotomy for chronic cervical zygapophyseal-joint pain." New England Journal of Medicine 335(23): 1721-1726. ***NB. This quality appraisal is largely based on the appraisal contained in the previous version of this report***

Description of study: randomised controlled trial – level I evidence

Patient/population	"…patients whose cervical zygapophyseal-joint pain had been confirmed with the use of local anesthetic blocks at either the unit or a private radiology practice in Newcastle." 9 males and 15 females; mean age, 43 years.
N	N=24, 12 in intervention arm and 12 in control arm.
Setting	Inpatient for intervention and outpatient for follow up.
Intervention	Radiofrequency denervation – "A 10-cm, 22-gauge electrode with a 4-mm exposed tip was introduced percutaneously, under fluoroscopic control, so that it contacted each of the two nerves supplying the painful joint. For each nerve the electrode was introduced twice; once along a parasagittal path to reach the nerve as it crossed the lateral aspect of the ipsisegmental articular pillar, and again at a 30-degree angle to the sagittal plane in order to reach the nerve over the anterolateral aspect of the pillar (Fig. 1). At each location two or three lesions were made, to accommodate possible variation in the course of the nerve. Lateral and anteroposterior radiographs were obtained of every placement of the electrode during which a lesion was made (Fig. 2)." In the process of lesioning, the temperature of the electrode tip was raised to 80°C for 90 seconds.
Control	As above, however instead of lesioning, the temperature of the electrode was maintained at 37°C.
Outcomes	Pain relief - Visual analogue scale, McGill Pain Questionnaire; Sensation of numbness.
Inclusion Criteria	"To enter the study, the patients had to have already been assessed by a specialist, had to have tried conventional therapy without success, and had to have been referred by a medical practitioner." "The study patients were selected from among patients whose cervical zygapophyseal-joint pain had been confirmed with the use of local anesthetic blocks at either the unit or a private radiology practice in Newcastle." "Patients with painful C3–4 to C6–7 zygapophyseal joints were included. To be eligible for the trial, patients had to have their perception of pain confirmed by placebo-controlled, diagnostic blocks."
Exclusion Criteria	"Patients with C2–3 zygapophyseal joint pain were excluded, because the pilot study had shown that treatment at this level by radio-frequency neurotomy was technically difficult."

Study Validity

Were there any conflicts of interest in the writing or funding of this study?	No	Authors were employed by University of Newcastle or Mater Misericordiae Hospital and the study was funded by a grant from the Motor Accidents Authority of New South Wales.
Does the study have a clearly focused question?	Yes	The question is whether radiofrequency denervation is effective for pain relief in people with cervical zygapophyseal-joint pain compared to control. Recognising the lack of evidence from controlled trials, they conduct an RCT in a specific population.
Is a RCT the appropriate method to answer this question?	Yes	
Does the study have specified inclusion/exclusion criteria?	Yes	As above.

If there were specified inclusion/ exclusion criteria, were these appropriate?	Yes	
Did the study have an adequate method of randomisation?	Yes	"The patients were assigned on the basis of a computer-generated schedule of random numbers…"
Was allocation to intervention group concealed?	Not reported	
Were patients blind to intervention group?	Yes	Apart from the application of temperature lesioning (or not for control), "In every other respect the procedures used in the two groups were identical." "Neither the patient nor the surgeon knew the patient's treatment assignment (the temperature of the electrode used) until the completion of the trial."
Were investigators and care providers blind to intervention group?	Yes	"One surgeon performed all the operations and made all the preoperative and postoperative assessments. Another operator controlled the radio-frequency generator. The device was masked so that the surgeon had no way of determining the temperature of the electrode tip." "During their operations, all the patients had adequate regional anesthesia, so no sensations of heat or pain compromised the blinding of the study. The surgeon could not determine which patients received the active treatment, either during the operation or subsequently."
Were outcome assessors blind to intervention group?	Yes	Post-operative assessment of pain by interview by surgeon and visual analogue scale and the McGill Pain Questionnaire - "Remaining unaware of the treatment assignments, the surgeon assessed each patient."
Aside from the experimental intervention, were the groups treated the same?	Yes	Apart from the application of temperature lesioning (or not for control), "In every other respect the procedures used in the two groups were identical."
Was there sufficient duration of follow-up?	Yes	"All the patients were contacted twice by telephone after their operations, at three to five days and at two to three weeks, and they were formally interviewed at three months." "Those whose relief continued for three months postoperatively were asked to telephone the study investigators as soon as their pain returned to at least 50 percent of the preoperative level. In addition, they were formally interviewed at 12 months and once a year thereafter."
All outcomes were measured in a standard, valid and reliable way?	Yes	Validated scales for pain relief - visual analogue scale, McGill Pain Questionnaire, SCL-90-R, global severity index. "A neurologic examination was performed to document any sensation of numbness." This was performed by the blinded surgeon outcome assessor.
Were outcomes assessed objectively and independently?	Yes	Validated scales for pain relief - visual analogue scale, McGill Pain Questionnaire, SCL-90-R, global severity index. "A neurologic examination was performed to document any sensation of numbness." This was performed by the blinded surgeon outcome assessor. "Once all the subjects had completed the three-month assessment, the randomization code was broken in a limited fashion. One member of the research team remained unaware of the treatment assignments in order to monitor the long-term progress of the patients who had continuing relief of pain." "Treatment was considered successful only if there was complete relief of pain, as corroborated by the visual- analogue scale and the McGill Pain Questionnaire, by the patient's report that he or she perceived no pain and needed no further treatment, and by the restoration of desired activities of daily living."

Was the study sufficiently powered to detect any differences between the groups?	Yes	"On the basis of data from a pilot study, our calculations of power indicated that a sample containing not less than 12 patients in each group would be required. The first 24 patients who met the criteria for the study were enrolled." "The sample we studied was small because, from an ethical viewpoint, subjecting patients to a sham operation that lasted three hours and involved risks of infection, exposure to radiation, and postoperative pain made it imperative to recruit as few patients as necessary."
If statistical analysis was undertaken, was this appropriate?	Yes	"Kaplan–Meier survival curves were constructed for both treatment groups, and the Mantel–Haenszel test was used to calculate the significance of the difference between the curves."
Were the groups similar at baseline with regards to key prognostic variables?	Yes	"There were no significant differences between groups with respect to age, sex, employment status, duration of pain, joints treated, or base-line scores on the visual-analogue scale, the McGill Pain Questionnaire, and the SCL-90-R. However, after randomization, the control group included more patients engaged in ongoing litigation related to their motor vehicle accidents." Table 1 also outlines baseline characteristics.
What percentage of the individuals recruited into each arm of the study dropped out?		"No patient was lost to follow-up."
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?	Not reported	It was not reported what the planned outcomes were and therefore we are unable to state if the article is free of selective reporting.
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 associated with the procedure*** lasted a median of 3.5 days (interquartile range, 1 to 16) in the control group and 13.5 days (interquartile range, 6 to 15) in the active treatment group (P = 0.26 by the Mann–Whitney U test)." "No patient in the control group had ***numbness*** that lasted longer than the patient's regional anesthesia. Five patients in the active-treatment group had ***numbness*** or dysesthesias in the cutaneous territory of the coagulated nerves (C3–4 in three patients and C4–5 and C5–6 in one patient each), but none rated these sensory changes as troublesome or requiring treatment." "Six patients in the control group and three in the active-treatment group had a ***return of their accustomed pain*** in the period immediately after the operation." "By 27 weeks, one patient in the control group and seven in the active-treatment group ***remained free of pain*** (Fig. 3)." "The ***median time to the return of at least 50 percent of the preoperative level of pain*** was 263 days in the active-treatment group and 8 days in the placebo group (P = 0.04 by the Mantel–Haenszel test)." "Patients engaged in litigation were no more likely to report relief from pain than nonlitigants in either group. "Two patients in the active-treatment group who had no relief from their pain were subsequently found to have pain from spinal segments adjacent to those treated, as if the treatment of the initial pain had uncovered a secondary source of pain. One such patient, who had incomplete relief after a C5–6 neurotomy, had pain mediated by the medial branch of C7. The other had pain from C2–3 in addition to C3–4."
"Five patients in each study group underwent ***second procedures***. Three patients in the active-treatment group, who had less than three months' relief after the first procedure, did not have relief of their pain after the second procedure. One patient in the control group had no relief after either the initial procedure (without active treatment) or the "escape" procedure (with active treatment). As of January 1996, the other six patients (two in the active treatment group and four in the control group) had complete relief lasting a median of 253 days (interquartile range, 186 to 397)."

Author's conclusions

"We found that radio-frequency neurotomy provided lasting, complete relief, but only in a moderate proportion of patients. Nevertheless, as shown in this study and previously, such relief can last for months to over a year, and if pain recurs the relief can usually be reinstated by repeating the procedure. By appraising the technique further and continuing to monitor our experience, we will attempt to improve the rate and duration of success." "Although we have shown that percutaneous radio-frequency neurotomy is significantly more efficacious than placebo, problems with the procedure remain. Despite apparently clear diagnoses, patients may obtain no relief even after more than one neurotomy. Others can have additional pain revealed after their original, dominant pain is treated. On the other hand, patients who have relief for a limited time after an initial operation sometimes have relief again after a second procedure, and for a longer time.

Our comments/summary

Limited evidence of benefit of radiofrequency denervation for relief of chronic neck pain The authors present a well conducted RCT, with low risk of bias, and with results suggesting the benefit of using radiofrequency denervation for relief of chronic neck pain as well as restoration of selected activities of daily living in a moderate proportion of patients (7 out of 12 treated patients remained pain free at 27 weeks). However, in the absence of other, and large, well conducted trials, radiofrequency denervation should be recommended cautiously, bearing in mind the limitations in study methodology as well as generalisability described by the authors e.g. small sample size, specific diagnostic method, specific radiofrequency denervation technique. "Our results apply only to patients responsive to double-blind, placebo-controlled, diagnostic blocks whose treatment involves multiple lesions of the target nerves. The results cannot be generalized to apply to patients whose pain is confirmed by less stringent criteria or who are treated with less exacting variants of the technique."

Table A5.5 Critical appraisal table (Alturi, 2008)

THORACIC **Study:** Atluri, S., S. Datta, et al. (2008). "Systematic review of diagnostic utility and therapeutic effectiveness of thoracic facet joint interventions." Pain Physician **11**(5): 611-629.	
Description of study: Systematic review of RCTs (or other types of studies).	
Patient/population	People with chronic mid back and upper back pain
N	Thoracic: "34 studies for radiofrequency neurotomy were identifies. Of these, 2 studies were identified which showed percutaneous facet denervation of medial branches. However, both of them failed to meet inclusion criteria, with low methodologic quality." **Studies not addressing radiofrequency denervation were also included in these evidence based guidelines but are not reported here.**
Setting	Not reported
Intervention/indicator	Thoracic: medial branch radiofrequency neurotomy (among other therapeutic facet joint interventions).
Comparison/control	Not reported
Outcomes	"The primary outcome measure was pain relief at various time points reported at least over a period of 6 months. The secondary outcome measures were functional status improvement, psychological status improvement, return to work, and complications. Short-term pain relief was defined as relief lasting 6 months or less and long-term relief as longer than 6 months."
Inclusion Criteria	"Studies should have documented the existence of thoracic spinal pain of facet joint origin using controlled diagnostic facet joint or nerve blocks. Three types of facet joint interventions were included in this review: intraarticular facet joint injections, medial branch blocks, and medial branch radiofrequency neurotomy. All studies must have provided appropriate management with outcome evaluations of at least 6 months and appropriate statistical analysis."
Exclusion Criteria	"Reports without appropriate diagnosis and elimination of false-positive responses, abstracts beyond 2 years, non-systematic reviews, book chapters, and case reports were excluded."

Study Validity.		
Is it clear that there were no conflicts of interest in the writing or funding of this review?	Not reported	
Does the review have a clearly- focused question?	Yes	"To determine the clinical utility of diagnostic and therapeutic thoracic facet joint interventions in diagnosing and managing chronic upper back and mid back pain."
Is a systematic review the appropriate method to answer the question?	Yes	
Does the review have specified inclusion/exclusion criteria?	Yes	See above

If there were specified inclusion/ exclusion criteria, were these appropriate?	Yes	
Does the review document a comprehensive search strategy?	Yes	"A comprehensive literature search was conducted which included search of databases including Medline and EMBASE from 1966 through July 2008, Cochrane database, Clinical Trial Registry, systematic reviews, narrative reviews, cross-references to the reviews, and peer-reviewed abstracts from scientific meetings (during the past 2 years), published in the English language. The search strategy emphasized chronic thoracic pain of facet joint origin with a focus on all types of diagnostic and therapeutic interventions. Search terminology included thoracic facet joint, thoracic facet joint pain, thoracic diagnostic facet joint blocks, thoracic facet joint intraarticular injections, medial branch blocks, and radiofrequency neurotomy."
Were reviewers blind to authors, institutions and affiliations?	Not reported	
Were 2 or more independent reviewers used for: **10. application of inclusion criteria to assess eligibility of studies?**	Yes	"Each study was evaluated by 2 physicians for stated criteria and any disagreements were resolved by the third physician."
11. extraction of data from study reports?	Not reported	
12. appraisal of study quality?	Yes	"The quality of each individual article used in this analysis was assessed by modified Cochrane review criteria with weighted scores for randomized trials and AHRQ quality criteria for assessment of observational studies for non-randomized trials with consensus-based weighted scoring developed by the guidelines committee of the American Society of Interventional Pain Physicians. Only the studies scoring at least 50 of 100 on weighted scoring criteria were utilized for analysis."
Were the strengths and limitations of included studies and potential impact on the results discussed?	N/A	No study has been included
Was the validity of included trials appraised using appropriate criteria?	Yes	"Qualitative analysis was conducted using 5 levels of evidence, ranging from Level I to Level III with subcategories in Level II, which defines short-term and long-term relief as illustrated in."
Is there a summary of the results of individual studies?	N/A	No study has met inclusion criteria (see results section below)
If meta-analyses were conducted, was it reasonable to do so?	N/A	
If meta-analyses were conducted, was it done appropriately?	N/A	

Other		
What is the overall risk of bias?	Low	*Low - All 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.* *Moderate - Some of the criteria have been fulfilled and those criteria that have not been fulfilled may affect the conclusions of the study.* *High - Few or no criteria fulfilled or the conclusions of the study are likely or very likely to be affected.* *Insufficient information – not enough information provided on methodological quality to be able to determine risk of bias.*

Results.

"The literature search revealed 34 studies for radiofrequency Neurotomy. Of these, 2 studies were identified which showed percutaneous facet denervation of medial branches. However, both of them failed to meet inclusion criteria, with low methodologic quality."

"The disadvantages of both the studies include retrospective evaluation without a comparative group, lack of diagnosis by controlled blocks, small number of patients, without adequate outcome measures, and statistical analysis."

The review also reported on diagnostic facet joint interventions, intra-articular facet joint blocks and medial branch blocks which were not part of our question.

Author's Conclusions.

"Based on the review of the included therapeutic studies described herein, no evidence synthesis is available for thoracic radiofrequency neurotomy."

Our Comments/Summary.

The study presents a low risk of bias. No studies investigating the therapeutic effectiveness of radiofrequency denervation for thoracic facet joint pain has been identified.

Table A5.6 Critical appraisal table (Chou, 2009)

LUMBAR **Study:** Chou, R., S. J. Atlas, et al. (2009).Nonsurgical interventional therapies for low back pain: a review of the evidence for an American Pain Society clinical practice guideline. Spine **34**(10): 1078-1093.		
Description of study: Systematic review of RCTs (or other types of studies).		
Patient/population	Patients with low back and radicular pain.	
N	9 RCTs (n= 494) **These participant and study numbers only represent those investigating radiofrequency denervation.**	
Setting	" The study is part of a larger evidence review commissioned by the American Pain Society to guide recommendations for evaluation and management of low back pain"	
Intervention/indicator	Radiofrequency denervation (among other therapeutic interventions) for:	
Comparison/control	Sham controls	
Outcomes	Radicularity with prolapsed lumbar disc Presumed facet joint pain Presumed discogenic low back pain	
Inclusion Criteria	"We included randomized controlled trials and systematic reviews meeting all of the following criteria: English language, or non-English language trial but included in an English language systematic review Evaluated nonpregnant adults (18 years old) with low (lumbar or sacral) back pain of any duration, alone or with leg pain Evaluated a target injection or other interventional therapy Reported at least 1 of the following outcomes: back specific function, generic health status, pain, work disability, or patient satisfaction"	
Exclusion Criteria	"We excluded trials of low back pain associated with acute major trauma, cancer, infection, *cauda equina* syndrome, fibromyalgia, spondyloarthropathy, and osteoporosis or vertebral compression fracture. We excluded outdated systematic reviews, which we defined as systematic reviews with a published update, or systematic reviews published before the year 2000. Intrathecal therapy, adhesiolysis, and intradiscal ozone injection are reviewed in the larger report. A separate article addresses surgical interventions for low back pain."	
Study Validity.		
Is it clear that there were no conflicts of interest in the writing or funding of this review?	Yes	"Professional Organization funds were received in support of this work. 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 review have a clearly- focused question?	Yes	"This article reviews current evidence on benefits and harms of nonsurgical interventional therapies for treatment of low back pain and radiculopathy, focusing on data from randomized controlled trials."
Is a systematic review the appropriate method to answer the question?	Yes	

Does the review have specified inclusion/exclusion criteria?	Yes	As above
If there were specified inclusion/ exclusion criteria, were these appropriate?	Yes	
Does the review document a comprehensive search strategy?	Yes	"We conducted searches (through July 2008) combining terms for low back pain with various interventional therapies in Ovid MEDLINE, the Cochrane Database of Systematic Reviews, and the Cochrane Central Register of Controlled Trials Electronic searches were supplemented by reference lists and additional citations suggested by experts. We did not include trials published only as conference abstracts."
Were reviewers blind to authors, institutions and affiliations?	Not reported	
Were 2 or more independent reviewers used for: **13. application of inclusion criteria to assess eligibility of studies?**	Yes	"Two reviewers independently rated the quality of these trials using the 11 criteria developed by the Cochrane Back Review Group (see Supplemental Digital Content 2, http://links.lww.com/A911). Discrepancies were resolved through joint review and a consensus Process"
14. extraction of data from study reports?	As above	
15. appraisal of study quality?	As above	
Were the strengths and limitations of included studies and potential impact on the results discussed?	Yes	"To assign an overall strength of evidence (good, fair, or poor), we considered the number, quality, and size of studies; consistency of results between studies; and directness of evidence Consistent results from a number of higher quality studies across a broad range of populations support a high degree of certainty that the results of the studies are true (the entire body of evidence would be considered "good quality"). For a "fair-quality" body of evidence, results could be due to true effects or to biases operating across some or all of the studies. For a "poor-quality" body of evidence, any conclusion is uncertain."
Was the validity of included trials appraised using appropriate criteria?	Yes	"We assessed overall strength of evidence for a body of evidence using methods adapted from the US Preventive Services Task Force."
Is there a summary of the results of individual studies?	Yes	The article presents a detailed description of the included studies' results (see results section below).
If meta-analyses were conducted, was it reasonable to do so?	N/A	
If meta-analyses were conducted, was it done appropriately?	N/A	

Other		
What is the overall risk of bias?	Low	

Results.

"Nine randomized trials evaluated radiofrequency denervation. Four trials were included in at least 1 of 5 systematic reviews and we identified 5 additional trials. Eight of 9 trials were placebo-controlled.

- **For presumed facet joint pain**, trials of radiofrequency denervation are difficult to interpret.

The only trial (n=40) to use controlled facet joint blocks to select patients and an ablation technique believed to be optimal found radiofrequency denervation superior to sham treatment by -1.4 to -1.6 points (0–10 visual analog scale [VAS] scale) for improvement in generalized, back, and leg pain after 6 months, but the difference was not statistically significant for back pain (the main symptom thought to be associated with facet pain). In addition, baseline pain scores in the radiofrequency denervation group averaged 1.6 points higher (P <0.05 for differences) than in the sham group, which suggests inadequate randomization and could be associated with regression to the mean or differential potential for improvement. Furthermore, final pain scores in both groups were identical. Three other trials met criteria to be classified as higher quality but used uncontrolled diagnostic facet joint blocks to select patients, may have used suboptimal techniques and reported conflicting results.
One trial (n=30) found radiofrequency denervation associated with moderately greater improvement in mean VAS pain (-2.4 *vs.* -0.4 on a 0–10 scale, *P* <0.05) and ODI scores (-11.1 *vs.* -1.7, *P* <0.05) *versus* sham through 2 months. Radiofrequency denervation was also associated with greater likelihood of experiencing at least a 2 point reduction in VAS pain score and greater than 50% improvement in global effect at 8 weeks (67% *vs.* 37.5%, *P*<0.003) and 12 months (46.7% *vs.* 12.5%, *P*<0.02).
The second trial (n=70) found radiofrequency denervation superior to sham treatment for mean improvement in RDQ scores at 4 weeks (-8.4 *vs.* -2.2, *P*<0.05), but there were no statistically significant differences in ODI or VAS pain scores. At 12 weeks, the difference in RDQ scores was no longer present.
The third trial (n=82) found no differences between radiofrequency and sham intervention on any outcome.
A lower quality trial (n=60) found conventional but not pulsed radiofrequency denervation superior to sham denervation for pain, the ODI, and analgesic use through 1 year. Effects on pain were small to moderate (0.8 –1.5 points on a 0–10 scale) and on the ODI were small (4–6 points). Another sham-controlled trial had serious methodologic shortcomings, including lack of intention-to-treat analysis.

Two higher-quality and 2 lower quality systematic reviews also found uncertain or inconsistent benefits associated with radiofrequency denervation for presumed facet joint pain, though none included the three most recently published sham-controlled trials. A fifth systematic review concluded there is moderate evidence supporting benefits from radiofrequency denervation. It excluded a higher quality trial with more neutral findings because it used a single block to identify facet joint pain, leaving only a single, small (n=31) higher quality randomized trial — which also did not appear to use controlled blocks to select patients — demonstrating benefits. This systematic review also included 10 observational studies, but criteria for classifying results of observational studies as positive were poorly described.

- **For presumed discogenic back pain with positive discography unresponsive to treatment with IDET:**

1 small (n=49), lower quality trial found radiofrequency denervation of the ramus communicans nerves associated with substantially better mean VAS pain scores (3.8 *vs.* 6.3 on a 0–10 scale, *P* <0.05), and moderately better SF-36 bodily pain (43.7 *vs.* 32.4, *P* _ 0.05) and physical function scores (58.9 *vs.* 46.5, *P*< 0.05) compared with lidocaine injection after 4 months.

- **For chronic radicular pain with a positive selective nerve root block**, 1 higher quality trial found no difference between radiofrequency denervation of the dorsal root ganglions and sham treatment for achieving clinical success (16% *vs.* 25%, *P* _ 0.43), improvement in SF-36 scores, or use of analgesics. There was a trend toward a higher proportion of patients in the sham intervention group that reported_50% reduction in VAS-pain scores for the leg (21% *vs.* 42%, *P*<0.051)."

One trial reported a case of mild, subjective, and transient lower limb weakness following radiofrequency denervation. Two other trials found no difference in adverse events between radiofrequency denervation and sham, though radiofrequency treatment was associated with trends toward increased postprocedural pain.

Author's Conclusions.

"There is insufficient (poor) evidence from randomized trials (conflicting trials, sparse and lower quality data, or no randomized trials) to reliably evaluate radiofrequency denervation."
Our Comments/Summary.
The study is a well conducted systematic review with a low risk of bias.

Table A5.7 Critical appraisal table (Rupert, 2009)

SACROILIAC **Study:** Rupert MP, Lee M, Manchikanti L, Datta S, Cohen SP. Evaluation of sacroiliac joint interventions: A systematic appraisal of the literature. Pain Physician. [Review]. 2009;12(2):399-418.		
Description of study: Systematic review of RCTs (or other types of studies).		
Patient/population	People with sacroiliac joint pain diagnosed with double-blocks	
N	1 SR of 3 observational studies (n=22, n=9, n=9). **Please note all these studies may not have assessed our outcomes of interest.**	
Setting	Not stated	
Intervention/indicator	For the 3 observational studies included in the SR: Vallejo et al 2006 (n=22): pulsed RFD Burnham & Yasui 2007 (n=9): bipolar radiofrequency neurotomy Cohen & Abdi 2003 (n=9): radiofrequency denervation. **Please note, not all of these interventions are relevant to this report**	
Comparison/control	None	
Outcomes	"The primary outcome measure was pain relief at various time points documented over a period lasting at least 6 months. Secondary outcome measures were functional improvement, psychological improvement, return-to-work, opioid use, and complications. Short-term relief was defined as relief lasting 6 months or less and long-term relief as benefits extending beyond 6 months."	
Inclusion Criteria	"Studies should have documented the existence of sacroiliac joint pain using controlled sacroiliac joint blocks. Two types of SI joint interventions were included in this review: intraarticular sacroiliac joint injections and radiofrequency neurotomy of the nerve supply to the sacroiliac joint. All studies must have documented outcome evaluations extending at least 6 months, with appropriate statistical analysis."	
Exclusion Criteria	"Studies done without appropriate diagnostic methods (i.e., minimizing false-positive responses, non-systematic reviews, book chapters, and case reports were excluded."	
Study Validity.		
Is it clear that there were no conflicts of interest in the writing or funding of this review?	No	The following statement on the paper "conflict of interest: none", and statements in the paper declaring that "If there was a conflict of interest with the reviewed manuscripts with authorship or any other type of conflict, the involved authors did not review the manuscripts for quality assessment, clinical relevance, evidence synthesis, or grading of evidence". However, there is still a *potential* conflict of interest as it was not reported whether this procedure was followed for determining eligibility for inclusion of studies in the review, and it was not reported whether the reviewers were blind to authors of articles that they were reviewing, meaning that even though the authors were not assessing their own papers, they were potentially assessing papers written by their colleagues, which could impact the results. However, the only RCT available on this topic was written by one of the review authors, and it was excluded from the review.

Does the review have a clearly- focused question?	Partial	"The purpose of this review is to systematically assess the literature on diagnostic and therapeutic sacroiliac joint interventions."
Is a systematic review the appropriate method to answer the question?	Yes	
Does the review have specified inclusion/exclusion criteria?	Yes	"Studies should have documented the existence of sacroiliac joint pain using controlled sacroiliac joint blocks. Two types of SI joint interventions were included in this review: intraarticular sacroiliac joint injections and radiofrequency neurotomy of the nerve supply to the sacroiliac joint. All studies must have documented outcome evaluations extending at least 6 months, with appropriate statistical analysis. Studies done without appropriate diagnostic methods (i.e., minimizing false-positive responses, non-systematic reviews, book chapters, and case reports were excluded...only English language articles were reviewed... Only studies scoring at least 50 out of 100 [for quality assessment] were included for analysis."
If there were specified inclusion/ exclusion criteria, were these appropriate?	Yes	
Does the review document a comprehensive search strategy?	Yes	"The literature search included the databases PubMed, EMBASE, and Cochrane reviews; systematic and narrative reviews; and the NIH clinical trials registry. The search included articles published between 1966 and 2008. A manual review of the reference section of selected articles was then performed to identify relevant studies missed in the electronic search. Only English language articles were reviewed. The search was conducted utilizing the following terms: sacroiliac joint, sacroiliac joint pain, sacroiliac joint injections, radiofrequency neurotomy of sacroiliac joint, neurolytic blocks of sacroiliac joint." Further information is needed about the combination of search terms to determine if the search was appropriate
Were reviewers blind to authors, institutions and affiliations?	Not reported	
Were 2 or more independent reviewers used for: **16. application of inclusion criteria to assess eligibility of studies?**	Not reported	
17. extraction of data from study reports?	Not reported	
18. appraisal of study quality?	Yes	"Each study was evaluated by 2 physicians for the stated criteria with any disagreements resolved by a third physician. If there was a conflict of interest with the reviewed manuscripts with authorship or any other type of conflict, the involved authors did not review the manuscripts for quality assessment, clinical relevance, evidence synthesis, or grading of evidence."
Were the strengths and limitations of included studies and potential impact on the results discussed?	Partial	The authors discuss the limitations of included studies, but not the potential impact of these limitations on the results of the studies

Was the validity of included trials appraised using appropriate criteria?	Yes	"The quality of each individual article used in this analysis was assessed by modified Cochrane review criteria with weighted scores (52) for randomized trials and AHRQ quality criteria for assessment for observational studies (43) with consensus-based weighted scoring developed by the guidelines committee of ASIPP (33) and used in other systematic reviews (44,47-50,53-61)"
Is there a summary of the results of individual studies?	Yes	
If meta-analyses were conducted, was it reasonable to do so?	N/A	
If meta-analyses were conducted, was it done appropriately?	N/A	
Other		
What is the overall risk of bias?	Low to Moderate	*Most of the criteria have been fulfilled and those criteria that have not been fulfilled may affect the conclusions of the study.*

Results.

"Based on this systematic review that included 5 studies evaluating the diagnostic accuracy of sacroiliac joint injections, the indicated evidence is Level II-2. For therapeutic interventions, there was no evidence supporting or refuting intraarticular injections. For radiofrequency neurotomy, the indicated evidence is Level II-3 or limited."
"The inclusion criteria formulated for this review considered only those studies in which a double-diagnostic block paradigm was used to establish a painful sacroiliac joint. This was done for several reasons. First it was felt that using true placebo blocks for diagnostic purposes are generally considered to be unethical and impractical. Yet, without the use of double comparative blocks, one cannot reliably eliminate false-positive responders. The use of double-blocks to select patients for lumbar facet joint interventions is far more consistent than for SI joint therapies (4,31,44,48-50,119-124). Further confounding the use of double-blocks in selecting candidates for sacroiliac joint denervation are the uncertainties and vagaries surrounding the nerve supply (125). This has led some investigators to suggest that double sacroiliac joint injections are the most reliable means to select treatment candidates. Despite our advocacy for double-diagnostic selection criteria, the disparities in published studies indicate that this is not a universally accepted criterion. Furthermore, what little literature does exist on this topic suggests that using double blocks prior to radiofrequency denervation may not improve treatment outcomes (126)"
This review also reported on diagnostic sacroiliac joint injections and therapeutic intraarticular injections, which were not part of our question.

Author's Conclusions.

This systematic review lends moderate support for the use of diagnostic sacroiliac joint interventions in chronic low back and/or lower extremity pain, whereas it provides limited evidence for radiofrequency neurotomy of sacroiliac joint nerve supply. Thus, a cautious approach must be utilized for diagnosis and even more cautious for therapeutic management, either with intraarticular injections or radiofrequency neurotomy based on individual patient circumstances and the clinician's experience and technical capabilities.

Our Comments/Summary.

Limited evidence of benefit of radiofrequency Denervation for relief of chronic sacroiliac joint pain
This review has a low to moderate risk of bias, mainly due to the fact that some authors of the review were also authors of studies being considered for inclusion. The authors state that "If there was a

conflict of interest with the reviewed manuscripts with authorship or any other type of conflict, the involved authors did not review the manuscripts for quality assessment, clinical relevance, evidence synthesis, or grading of evidence" However, it was not reported whether this procedure was followed for determining eligibility for inclusion of studies in the review, and it was not reported whether the reviewers were blind to authors of articles that they were reviewing, meaning that even though the authors were not assessing their own papers, they were potentially assessing papers written by their colleagues. This has the potential to impact on the findings of the review if it were to effect which studies were included in the review.

It is important to note that despite this potential source of bias for study selection, the only RCT available on RFD for sacroiliac joint pain was written by one of the review authors, and it was excluded from the review.

Overall there is limited evidence of the benefit of RFD for relief of chronic sacroiliac joint pain. This Systematic Review is based on three observational studies (n=22, n=9, n=9), the largest of these involved pulsed RFD, which is not relevant to this report.

Table A5.8 Critical appraisal table (Cohen, 2008)

SACROILIAC Study: Cohen SP, Hurley RW, Buckenmaier CC, 3rd, Kurihara C, Morlando B, Dragovich A. Randomized placebo-controlled study evaluating lateral branch radiofrequency denervation for sacroiliac joint pain. Anesthesiology 2008;109(2):279-88. *NB. This quality appraisal is largely based on the appraisal contained in the previous version of this report*	
Description of study: randomised controlled trial – level II evidence	
Patient/population	People with injection-diagnosed sacroiliac joint pain.
N	Control = 14 Radiofrequency denervation = 14
Setting	Outpatient at Johns Hopkins Medical Institutions, Baltimore, Maryland, and Walter Reed Army Medical Centre, Washington, D.C.
Intervention/indicator	Radiofrequency denervation procedure with current.
Comparison/control	Placebo: radiofrequency denervation procedure without current.
Outcomes	Primary outcome: pain Secondary outcome: function, reduction in analgesic medications, global perceived effect (GPE), duration of pain relief, composite successful outcome and complications.
Inclusion Criteria	"Inclusion criteria included age older than 18 yr; axial low back or buttock pain of 6 months or longer; tenderness overlying the sacroiliac joint(s); failure to respond to conservative therapy (e.g., physical therapy and pharmacotherapy), including long-term (>2 months) pain relief with sacroiliac joint corticosteroid injections; and pain relief of 75% or greater as calculated from a 6-h post-block pain diary after a single diagnostic sacroiliac joint injection."
Exclusion Criteria	"Exclusion criteria were focal neurologic signs or symptoms; radiologic evidence of a symptomatic herniated disc; spondyloarthropathy; untreated coagulopathy; and unstable medical (e.g., unstable angina) or psychiatric illness (e.g., untreated depression) that might preclude an optimal treatment response."

Study Validity		
Were there any conflicts of interest in the writing or funding of this study?	No	
Does the study have a clearly focused question?	Yes	
Is a RCT the appropriate method to answer this question?	Yes	
Does the study have specified inclusion/exclusion criteria?	Yes	As above.
If there were specified inclusion/ exclusion criteria, were these appropriate?	Yes	
Did the study have an adequate method of randomisation?	Yes	"Study patients were randomized in a 1:1 ratio to receive either true or placebo denervation."
Was allocation to intervention group concealed?	Yes	"A research nurse not involved in patient care performed randomization in blocks of four via presealed envelopes at each institution."

Were patients blind to intervention group?	Yes	As above. "After satisfactory electrode placement, 0.5 ml lidocaine, 2%, was injected through each cannula to reduce thermal pain and ensure blinding."
Were investigators and care providers blind to intervention group?	Yes	"All subjects were treated by a physician not involved in randomization."
Were outcome assessors blind to intervention group?	Yes	"A physician unaware of the patient's study group assignment obtained all outcome data during scheduled follow-up visits. Between the procedure and first follow up, no contact was permitted between any patient and investigator except for emergencies."
Aside from the experimental intervention, were the groups treated the same?	Yes	
Was there sufficient duration of follow-up?	Partial	1, 3 and 6 months. However, data is only presented for the placebo and intervention groups at 1 and 3 months. At 6 months, only data for the intervention group is presented. "For those who obtained significant relief 1 month after the procedure, unblinding was done 3 months after treatment."
All outcomes were measured in a standard, valid and reliable way?	Yes	"The primary outcome measure was a 0–10 NRS pain score, which reflected the average pain experienced by the patient for 10 days before follow-up. Secondary outcome measures included Oswestry disability index score (ODI version 2.0; MODEMS, Des Plaines, IL; reflecting the 10 days before follow-up), reduction in analgesic medications (defined as a 20% reduction in opioid use or complete cessation of a nonopioid analgesic), GPE, and a composite successful outcome."
Were outcomes assessed objectively and independently?	Yes	Validated scales were used and unvalidated scales were described where appropriate. As above.
Was the study sufficiently powered to detect any differences between the groups?	Yes	"A two-tailed power analysis determined a sample size of 14 in each group had 80% power (β of 0.2) to detect a 2-point difference in the 0–10 numeric rating scale (NRS) between groups with a significance level (α) of 0.05."
If statistical analysis was undertaken, was this appropriate?	Yes	"The Shapiro-Wilk W test for normal data was performed on continuous outcome measures. The distribution of categorical variables in each group was compared using the Fisher exact test. Continuous variables are reported as mean and SD or median and interquartile range. Categorical data are reported by number of subjects and percentage. Comparisons between the initial radiofrequency treatment group and the placebo group were made with unpaired t tests or the Mann–Whitney U test." "For multiple significance testing, a post hoc Bonferroni correction was used. Because baseline ODI differences were a potential confounding factor, an adjusted multiple linear and logistic regression analysis was performed for each continuous and categorical outcome measure, respectively."
Were the groups similar at baseline with regards to key prognostic variables?	Yes	"Demographic (including active duty status) and clinical characteristics were balanced between the radiofrequency denervation treatment and control group."
What percentage of the individuals recruited into each arm of the study dropped out?	0% treatment 0% control/ comparison	

Were all the subjects analysed in the groups to which they were randomly allocated (ie intention to treat analysis)?	Yes	Important to note: "All placebo patients who did not achieve a positive outcome were offered the opportunity to cross over and receive sacroiliac joint denervation using conventional (noncooled) technology in an open-label parallel arm." However, "Data from the crossover group were analyzed separately from those of the initial experimental group."
Is the paper free of selective outcome reporting?	No	It was not reported what the planned outcomes were, however statistical significance was not reported for all outcomes.
Were the outcomes measured appropriate?	Yes	"The primary outcome measure was a 0–10 NRS pain score, which reflected the average pain experienced by the patient for 10 days before follow-up. Secondary outcome measures included Oswestry disability index score (ODI version 2.0; MODEMS, Des Plaines, IL; reflecting the 10 days before follow-up), reduction in analgesic medications (defined as a 20% reduction in opioid use or complete cessation of a nonopioid analgesic),16 GPE, and a composite successful outcome."
Other	At 6 months, participants in the placebo group were offered the option to cross over into the radiofrequency denervation group. This section of the study was not randomised and the analysis was separated from the randomised section of the study. Therefore, for this review, only the data from the first randomised section of the study is considered.	
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

RFD = radiofrequency denervation **Pain (numerical rating pain scores stratified by treatment group and time point)** 1 Month Mean (SD, range): Placebo = 6.3 (2.4, 2–10) RFD = 2.4 (2.0, 0–8) p<0.001 Median (interquartile range): Placebo = 7 (4–7) RFD = 2 (1–3) 3 Months Mean (SD, range): Placebo = 6 (0, 6–6) RFD = 2.4 (2.3, 0–7) p not reported Median (interquartile range): Placebo = 6 (6–6) RFD = 1.5 (1–4.5) **Function (Oswestry Disability Index)** 1 Month Mean (SD, range): Placebo = 43.6 (14, 16–70) RFD = 20.9 (10.9, 4–38) p<0.03 Median (interquartile range): Placebo = 41 (34–56) RFD = 19 (14–29) 3 Months Mean (SD, range): Placebo = 24 (8.5, 18–30) RFD = 18.5 (11.6, 0–36) p not reported Median (interquartile range): Placebo = 24 (18–30) RFD = 20 (9.5–27) **Percent positive Global Perceived Effect stratified by treatment group and time point** 1 Month % (95% CI): Placebo = 21 (2–45) RFD = 93 (78–100) p<0.05 but text reports p<0.001 3 Months % (95% CI): Placebo = 0 RFD = 83 (59–100) **Positive percent medication reduction stratified by treatment group and time point** 1 Month % (95% CI): Placebo = 8 (0–25) RFD = 77 (52–100) p<0.05 but text reports p<0.001 3 Months % (95% CI): Placebo = 0 RFD = 82 (55–100) **Percent successful treatment** "The proportion of subjects who experienced a "positive outcome" was significantly higher in the denervation group than in the control group (P<0.001)." Only graph presented.

Duration of pain relief Mean (SD, range): Placebo = 0.7 (1.6, 0-1) months RFD = 5.8 (4.2, 0-12) months **Complications** "A majority of patients reported temporary worsening pain typically lasting between 5 and 10 days after the procedure, which was attributed to procedure-related pain and/or temporary neuritis; the latter may be attenuated by preemptive corticosteroid administration. However, there were no serious complications reported for either the 14 placebo or the 25 radiofrequency treatments. In the radiofrequency treatment group, one patient reported transient nonpainful buttock paresthesias that resolved without therapy." It is important to note that the 25 radiofrequency treatments include those that non-randomly crossed over from placebo after the initial six months.

Author's conclusions

"…the results of this placebo-controlled study provide preliminary support for the use of radiofrequency denervation to treat presumptive sacroiliac joint pain. Larger, multicenter studies with long-term follow-up and comprehensive outcome measures are needed to confirm our findings, further establish safety, and determine how best to identify candidates for this treatment."

Our comments/summary

The authors present a well conducted RCT, with low risk of bias, and with results suggesting the benefit of using radiofrequency denervation for short term (1 month) relief of sacroiliac pain, function, GPE, medication reduction and duration of pain relief. It is important to note that p values were not presented for the findings at the 3 month time point, therefore it is difficult to draw conclusions about these data. The trial authors acknowledge that larger, multicenter studies with long-term follow-up and comprehensive outcome measures are needed to confirm these findings, further establish safety, and determine how best to identify candidates for this treatment.