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.

Transport Accident Commission & WorkSafe Victoria

Evidence Service

Spinal Injection Therapies: Radiofrequency Denervation

Evidence Review

October 2010

Driss Ait Ouakrim, Emma Donoghue

A joint initiative of

CONTENTS

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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	Not reported

outcomes?	
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

The information in this report is a summary of that available and is primarily designed to give readers a starting point to consider currently available research evidence. Whilst appreciable care has been taken in the preparation of the materials included in this publication, the authors and the National Trauma Research Institute do not warrant the accuracy of this document and deny any representation, implied or expressed, concerning the efficacy, appropriateness or suitability of any treatment or product. In view of the possibility of human error or advances of medical knowledge the authors and the National Trauma Research Institute cannot and do not warrant that the information contained in these pages is in every aspect accurate or complete. Accordingly, they are not and will not be held responsible or liable for any errors or omissions that may be found in this publication. You are therefore encouraged to consult other sources in order to confirm the information contained in this publication and, in the event that medical treatment is required, to take professional expert advice from a legally qualified and appropriately experienced medical practitioner.

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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