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 be clear about the benefits and harms of RFD in the treatment of persistent pain in the neck (cervical spine), upper back (thoracic spine), lower back (lumbar spine) or where the spine meets the pelvis (sacroiliac joint).

Possible harms from RFD to the neck include minor numbness, unpleasant sensations and skin rash. For RFD to the lower part of the back, and where the spine meets the pelvis, possible harms include short-term worsening of pain and pins and needles.

National Trauma Research Institute

ISCRR
Institute for Safety, Compensation and Recovery Research

Spinal Injection Therapies: Radiofrequency Denervation

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For Transport Accident Commission and Victorian WorkCover Authority

Accompanying documents to this report

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EVIDENCE REVIEW SUMMARY

Spinal Injection Therapies: Radiofrequency Denervation

We searched for RCT's and systematic reviews which evaluated the effect of radiofrequency denervation in facet joint pain. Overall we identified:

- One RCT for cervical facet joints
- One systematic review of case series and one RCT for thoracic facet joints
- Eight RCT's for lumbar facet joints
- Two RCT's for sacroiliac joints

Key messages

Cervical facet joint
There is one small moderate quality study to validate the use of RFD in clinical practice.

Thoracic facet joint
There is insufficient evidence to validate the use of RFD in clinical practice.

Lumbar facet joint
There is low quality evidence which is unable to validate the use of RFD in clinical practice.

Sacroiliac facet joint
The evidence to validate the use of RFD in clinical practice is conflicted.

Purpose

The Transport Accident Commission (TAC) and the Victorian WorkCover Authority (VWA) requested a review of the evidence to determine whether RFD is an effective treatment compared to placebo in facet joint pain (cervical facet joints, thoracic facet joints, lumbar facet joints, and sacroiliac joints). This review sought to find the most up-to-date, high quality source of evidence to answer the following questions:

- In what conditions is RFD indicated?
- What is the effectiveness of RFD 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 RFD contraindicated?
- What are the risks associated with use of RFD?

- What is the impact of training and/or experience of practitioners on patient outcomes?

Rationale

To ensure funding decisions made regarding the use of RFD are evidence-based and in the best interests of injured Victorians.

New research relevant to RFD is regularly being published. This review is important for VWA/TAC as it provides an independent, thorough search and quality assessment of the peer-reviewed literature in this area. This can then be used to support funding decisions regarding this treatment. It can also be repeated in the future to incorporate new evidence as it arises.

Methods

Systematic review methods were used. A comprehensive search of Medline, Embase, the Cochrane Library, and All EBM was undertaken in April 2014 to identify relevant research. Reference lists of included studies were also scanned to identify relevant references.

Studies identified by the searches were screened for inclusion. In this review studies were only included if they were SRs, RCTs or CCTs that investigated the effects of RFD compared with placebo (or other active treatments) in patients with facet joint pain. Evidence that met the selection criteria was reviewed 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.

Research findings& implications

In what conditions is radiofrequency denervation (RFD) indicated?

Based on our review we are unable to determine patients would benefit most from RFD as studies which included patients with correctly diagnosed facet joint reported the same results as those that recruited based on less rigorous diagnostic methods

What is the effectiveness of RFD on persistent spinal pain and other patient relevant outcomes in facet joint pain?

Cervical Facet Joint Pain

Based on one small RCT (Lord1996) there is moderate level evidence to support the use of RFD for cervical facet joint pain. Further higher quality studies are required to determine whether these results can be replicated.

Thoracic Facet Joint Pain

There is insufficient evidence to determine the effect of RFD on thoracic facet joint pain compared to placebo. There is moderate level evidence based on one RCT that alcohol ablation to be more effective than RFD. The clinical utility of these finding for facet joint pain is uncertain given that alcohol ablation is not recommended for non cancer pain.

Lumbar Facet Joint Pain

Only low quality evidence exists for RFD and lumbar facet joint pain. All of these studies had 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 whether or not RFD is effective for lumbar facet joint.

Sacroiliac Facet Joint Pain

Based on two moderate level RCT's the overall effect of RFD on sacroiliac facet joint pain is unclear given that the studies reported conflicting results. These studies also have unique methodological and technical issues, which impact on the validity of their results.

In what patient groups/conditions is RFD contraindicated?

This was not reported by any of the included studies

What are the risks associated with use of RFD?

The risks identified for RFD included:

Cervical Facet Joint

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.

Thoracic Facet Joint

Pain in the deep soft tissue of the injection site was experienced by five of the RFD group. The pain subsided within 24 hours.

Lumbar facet Joint

Adverse effects were reported in two studies (Civelek 2012, van Wijk 2005). Civelek (2012) reported receiving complaints of small superficial burns following RFD (no further information provided) that resolved after 6-8 weeks. The other study (van Wijk 2005) reported two patients in the RFD group having discrete loss of motor function (compared to one patient in the sham group) and one patient who underwent RFD reporting of dysaesthesia (no reports in sham group).

Sacroiliac facet joint

Risks associated with lumbar facet joint was not reported

What is the impact of training and/or experience of practitioners on patient outcomes?

The issue of training was not explored in any of the included studies

BACKGROUND

Facet joints (also called zygapophyseal joints) are a pair of small joints, situated above and below each vertebral level of the spine, which provide stability and help guide motion. Two nerves called “medial branches”, which run along the facet joints, carry pain signals to the spinal cord, which are then directed to the brain (Australian and New Zealand College of Anaesthetists).

The prevalence of facet joint pain differs between studies with prevalence of cervical facet joint pain varying from 54% - 60%, thoracic pain 42% - 48% and low back pain 15% - 45% (Boswell 2005, Boswell 2007). Some argue that this wide variation is a result of the diagnostic methodology used to detect facet joint pain (Cohen 2007). Due to this variation in diagnosis some investigators believe that the only valid method of ascertaining facet joint pain is by controlled, guided intra-articular or medial branch blocks (Manchikanti 1999, Manchikanti 2000).

There are several conservative approaches in the management of facet joint pain including but not restricted to rest, pharmacotherapy, exercise therapy and alternative treatment (e.g. using hot pads and cold packs alternatively, yoga, Pilates, acupuncture and massage) (Van Zundert 2012, Perry 2014). In patients who do not respond to conservative management, Radio Frequency Denervation (RFD) or radiofrequency neurotomy of the medial branches of the affected facet joint(s) is an option.

RFD is a procedure in which an electrode is used to generate heat to coagulate the nerve and prevent it from transmitting painful signals to the brain. It does not remove the cause of the pain. This procedure involves x-ray fluoroscopy to guide an insulated electrode with an exposed tip into the spinal area parallel to the target nerve.(Murtagh 2006) A current is then passed through the electrode destroying the adjacent tissue, including the target nerve, so that the transmission of pain signals are interrupted (Murtagh 2006). The coagulation process is dependent on a number of factors including: the electric current used and the size of the electrode, the temperature generated, the duration of the procedure, impedance (i.e. resistance to the passage of an alternating current), identifying the correct joints and the application of correct RFD technique (Bogduk 2014).

In Australia radiofrequency denervation is approved under the Medicare Benefits Scheme under item number 39118 "PERCUTANEOUS NEUROTOMY for facet joint denervation by radiofrequency probe or cryoprobe using radiological imaging control" (Department of Health http://www.mbsonline.gov.au/internet/mbsonline/publishing.nsf/Content/Home).

Even though RFD is considered a standard treatment for chronic facet joint pain (Boswell 2007, Bogduk 2005, Nath 2008), there seems to be a lack of strong consensus about the correct technique and the tools that should be used; including the correct position of the electrode, the temperature and the duration necessary and how many lesions should be made (Van Zundert 2012, Bogduk 2014, Nath 2008, Bogduk 2009, Tekin 2007, van Wijk 2005). There is also controversy around how patients are selected for RFD, with regards to diagnosing facet joint pain, with some clinicians advocating controlled medial branch blocks

(Bogduk 2005), while others argue that proceeding to radiofrequency denervation without a diagnostic block may be more cost effective (Cohen 2010).

Given this uncertainty the Transport Accident Commission and the Victorian WorkCover Authority (TAC/VWA) Health and Disability Strategy Group has requested a systematic review of the evidence on RFD in order to develop and update their policies for the use of this technique in patients with chronic pain.

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 RFD indicated?
- What is the effectiveness of RFD on persistent spinal pain in these conditions?
- What is the effect of RFD on function (physical, psychological, social), quality of life, return to work, medication use and healthcare utilisation?
- In what patient groups/conditions is RFD contraindicated?
- What are the risks associated with use of RFD?
- What is the impact of training and/or experience of practitioners on patient outcomes?

METHODS

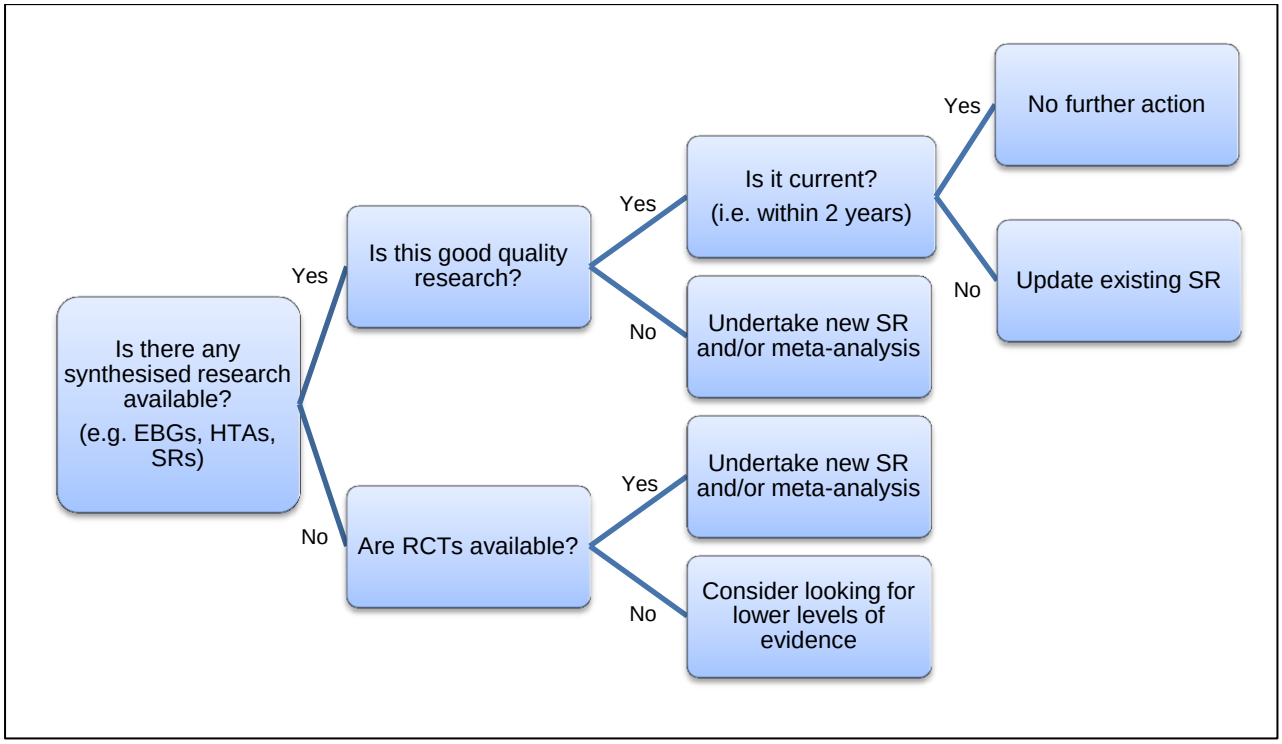
Methods are outlined briefly below. More detailed information about the methodology used to produce this report is available in Appendices 1 and 2 that are located in the Technical Report accompanying this document.

A comprehensive search of Medline, Embase, the Cochrane Library, All EBM, and CINAHL was undertaken in April 2014 to identify relevant synthesised research (i.e. evidence-based guidelines (EBGs), systematic reviews (SRs), health technology assessments (HTAs)), randomised controlled trials (RCTs) and controlled clinical trials (CCTs). Reference lists of included studies were also scanned to identify relevant references.

Studies identified by the searches were screened for inclusion using specific selection criteria (see Appendix 2, Table A2.1). In this review studies were only included if they were SRs, RCTs or CCTs that investigated the effects of RFD compared with sham or active treatment in patients with facet joint pain. Evidence that met the selection criteria were reviewed 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. Two reviewers conducted all screening and selection independently, results were compared and any discrepancies discussed and resolved.

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

Figure 1. Further action required to answer clinical questions



Data on characteristics of all included studies were extracted and summarised (see Table 1 and Appendix 4 of the Technical Report).

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 1), and the algorithm in Figure 1 was followed to determine the next steps necessary to answer the clinical questions.

Data on characteristics of all included studies were extracted and summarised (see Appendix 4, Technical Report). The most recent, comprehensive, high quality EBG or systematic review for each anatomical location was used to address the questions posed above.

RESULTS

We conducted a search in April 2014. The search yielded 1821 potential relevant journal articles after duplicate citations were removed. After reviewing the title and abstracts, 108 full texts were reviewed.

Table 1. 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	24
Thoracic	0	5	1	6
Lumbar	7	14	8	29
Sacroiliac	1	6	2	9

Results are reported below by anatomical location.

1. CERVICAL FACET JOINTS

Evidence identified

An initial assessment of the three most up-to-date synthesised studies, found that all used a single RCT (Lord 1996) 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. Because of this, an independent review of the RCT by Lord (1996) was conducted (see Table 1.1).

Study Characteristics

This study recruited 24 patients with cervical zygapophyseal-joint pain confirmed by placebo controlled diagnostic blocks; that had failed conventional management. Patients with C2–3 zygapophyseal joint pain were excluded as radio-frequency neurotomy at this level was technically difficult. Patients were then randomised to receive RFD at 80°C for 90 seconds or sham with the temperature of the electrode maintained at 37°C.

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).

The median time to the return of at least 50% 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–Hansel test).

Discussion

There is moderate level evidence in support of radiofrequency denervation for relief of chronic neck pain (Table 1.2). However these results are base on one small study. Larger studies replicating these results would strengthen the credibility of these results.

Table 1.1. Key information from most recent, high quality primary study for cervical facet joints

Lord SM, Barnsley L, Wallis BJ, McDonald GJ and Bogduk N. Percutaneous radio-frequency neurotomy for chronic cervical zygapophyseal-joint pain. New England Journal of Medicine (1996) 335(23): 1721-1726.	
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^{o}C for 90 seconds during lesioning **Control:** identical procedure, but electrode temperature maintained at 37^{o}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".
Conclusion/Recommendation	Overall this study provides limited evidence of benefit of radiofrequency Denervation for relief of chronic neck pain. 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."
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)

Table 1.2. Summary of findings table for cervical facet joints

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk **Sham**	Corresponding risk **RFD**				
Pain free status Follow-up: mean 27 weeks	**Study population**		**OR 0** (0 to -0.18)	24 (1 study)	⊕⊕⊕⊖ **moderate**[1]	
	83 per 1000	**0 per 1000** (0 to -17)				
	Moderate					

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **OR:** Odds ratio;

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] Small sample size (n=24)

2. THORACIC FACET JOINTS

Evidence Identified

We identified five systematic reviews (Lord 1996, Falco 2012, Hansen 2012, Joo 2013, Manchikanti 2012) addressing radiofrequency denervation for the treatment of chronic pain of thoracic origin and one RCT (Lakemeier 2013) (Table 1).

RFD vs Placebo

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 published in 2012 (Manchikanti 2012). Table 2.1 shows key information extracted from this study, a quality appraisal can be found in Appendix 5, Table A5.2. of the technical report.

Manchikanti (2012) identified two retrospective case series. 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 joint origin.

RFD vs Alcohol Ablation

There was only one RCT (Joo 2013) which compared RFD with alcohol ablation.

Study Characteristics

This trial included patients with recurrent thoracolumbar facet joint syndrome diagnosed by controlled comparative local anaesthetic blocks that had received successful radiofrequency medial branch neurotomy (RFD). In this study, patients were considered to have recurrent thoracolumbar facet joint syndrome (after successful RFD) if they had a visual analog Scale (VAS) pain score ≥ 7 and revised Oswerstry Disability Index (ODI) ≥ 22%.

These patients were randomised to receive RFD (n=20) or alcohol ablation (AA) (n=20). The RFD procedure involved placing a RFDE -10, 22-gauge, 10cm disposable electrode with a 10mm exposed tip, parallel to the targeted nerves along the expected course of the nerve at the base of the transverse process. Lesioning was performed at 90° for 90 seconds. In the AA group needles were placed between the posterior epidural surface and facet joint, which was followed by an injection of contrast medium, which was carefully measured to avoid leakage into the posterior epidural surface. The same volume of dehydrated alcohol was then injected over 15 seconds to avoid unwanted spread.

Patients were then followed up at 3 months intervals up to 24 months to assess the proportion of patients that were free of recurrence of thoracolumbar facet joint pain, defined as VAS pain score ≤ 7 and revised ODI ≤ 22%.

Study Quality

Despite the study being a randomised controlled trial that measured outcomes in a standard, valid and reliable way and assessed their results using appropriate statistical methods at relevant time points, the overall risk of bias is unclear as a number of key criteria such as method of randomisation, concealment of allocation and number of patients lost to follow-up was not reported. It may be that the randomisation method was adequate given that there was no significant difference between the groups regarding baseline and demographic characteristics, although we cannot be certain of this. In addition we don't know the number of patients on which the results were based as this was not reported.

Results

There were significantly more patients with recurring pain in the RFD group (n=19% vs 3%). The treatment effect was sustained significantly longer according to the log rank test. Median effective period was 24 months for RFD (range 16.8–24) vs.10.7 months for AA (range 5.4–24), based on the Kaplan–Meier product limit estimates (p<0.001).

Variations in potential confounding factors such as the location of the first RFD site (unilateral/bilateral), previous level of procedure (thoracic, lumbar, or thoracolumbar), previous fusion surgery, previous vertebroplasty or kyphoplasty due to osteoporotic compression fracture, or severe kyphoscoliosis did not affect the duration of pain relief using the Cox proportional hazards test p<0.001.

No significant complications were identified except for pain in the deep soft tissue of the injection site in five and seven patients in the repeated RFD and AA groups. The pain subsided within 24 h in both groups.

Discussion

Although it would appear that AA is more effective than RFD for thoracic facet joint pain the validity of these results are unclear as they are based on one small moderate quality study (Table 2.3), which did not provide sufficient information (regarding its methods and patient numbers in the analysis). Furthermore interpretation of these results in terms of policy and clinical decisions on the use of RFD is unclear given that chemical denervation is not recommended for the routine care of non-cancer patients with chronic pain.

Table 2.1. Key information from most up-to-date, high quality study for thoracic facet joint

Manchikanti KN, Atluri S, Singh V, Geffert S, Sehgal N, Falco FJE. An update of evaluation of therapeutic thoracic facet joint interventions. Pain Physician (2012) 15 (4 PG - E463-81) p. E463-81.	
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 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. There is no high quality evidence evaluating the effect of RFD on thoracic facet joint pain
Recommendation category	Insufficient evidence
Quality assessment results	Low risk of bias

Table 2.2. Key information from most up-to-date, high quality study for thoracic facet joint

Joo YC, Park JY, Kim KH. Comparison of Alcohol ablation with repeated thermal radiofrequency ablation in medical branch neurotomy for the treatment of recurrent thoracolumbar facet joint pain. Journal of Anaesthesia (2013) 27: 390-395.	
Study design	RCT
Scope	The aim of this study was to compare the effectiveness and safety alcohol ablation with RFD in patients with recurrent thoracic facet joint pain after successful RFD.
Effectiveness of RFD in persistent pain	• Significant difference in recurrence ratios between RFA and AA during 24 month follow up (19% for RFA and 3% in AA group. • Treatment effect of alcohol ablation (AA) compared to that of the radiofrequency ablation (RFA) censored 24-month data was sustained longer according to the log rank test. Median effective period in the AA group was significantly longer than RFA group 24 (range 16.8–24) vs. 10.7 (range 5.4–24) months, respectively] based on the Kaplan–Meier product limit estimates ($p < 0.001$) • Variations such as the location of the first RFA site (unilateral/bilateral), previous level of procedure (thoracic, lumbar, or thoracolumbar), previous fusion surgery, previous vertebroplasty or kyphoplasty due to osteoporotic compression fracture, and severe kyphoscoliosis did not affect the duration of pain relief using the Cox proportional hazards test. *$p < 0.001$
Effect of RFD on function (Physical, psychological, social), quality of life, return to work, medication use, healthcare utilisation	Not reported
Risks associated with RFD	No significant complications were identified except for pain in the deep soft tissue of the injection site in five and seven patients in the repeated RFA and AA groups. The pain subsided within 24 h in both groups.
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	Alcohol ablation may provide longer relieve of thoracic facet joint pain. This result is based on a small single study, whose results could not be confirmed due to inadequate reporting of study methods and results.
Recommendation category	Insufficient evidence
Quality assessment results	Unclear risk of bias

Table 2.3. Summary of findings table for thoracic facet joints

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk **Alcohol ablation**	Corresponding risk **RFD**				
Pain free status Follow-up: mean 24 months	**Study population**		**OR 0.00** (0.00 to 0.1)	40 (1 study)	⊕⊕⊕⊖ **moderate**[1]	
	850 per 1000	**0 per 1000** (0 to 362)				
	Moderate					

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **OR:** Odds ratio;

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] Small sample size (n=40).

3. LUMBAR JOINTS

Evidence Identified

The most comprehensive synthesised studies on RFD for lumbar facet joint pain were two systematic reviews (Falco 2012, Poetscher 2014). Of these the review by Poetscher (2014) included eight RCT's, while Falco (2012) only included six (excluding two based on poor diagnostic or surgical technique).

Despite the comprehensiveness of the review by Poetscher (2014), it did not provide adequate information on the risk of bias for the individual studies and did not adequately report or discuss the results. We therefore conducted an independent systematic review of all relevant RCTs on RFD for lumbar facet joint pain. Using the Cochrane Handbook of Systematic Reviews (Higgins JPT 2011) we assessed the methodological quality of the studies and transformed the data so that change from baseline scores could be compared across studies. We also presented the results as forest plots, without a meta-analysis, as there was too much uncertainty regarding patient selection and RFD technique across studies to warrant pooling the results.

We also assessed the diagnostic criteria for the inclusion of patients in each of the studies as well as the surgical technique using the International Spinal Injection Society's (ISIS) "Practice Guidelines for Spinal Diagnostic and Treatment Procedures" (Bogduk 1997).

Characteristics of Included Studies

We identified eight RCTs, consistent with the studies included in Poetscher (2014). Of these, six compared RFD with sham and two compared RFD with steroid/local anaesthetic injections. The number of participants included in the studies was relatively small and varied from 31 (van Kleef 1999) to 100 (Civelek 2012).

Duration of Pain

Two studies (Gallagher 1994, Leclaire 2001) specifically included patients with pain of more than three months duration (no baseline data on group specific duration provided). Another two studies recruited patients with pain of at least six months duration (Tekin 2007, van Wijk 2005). The mean duration of pain in Tekin (2007) for RFD patients was of 37.5 months and, 32.8 for sham patients. In van Wijk (2005), 77% of RFD patients had more than two years of back pain compared to 68% in the sham group. The study by van Kleef (1999) required patients to have more than 12 months of back pain to be recruited (RFD group had a median of 26 [range 12-120 months)] compared to sham median of 48 [range 12-192]). Both Lakemeier (2013) and Nath (2008) included patients with greater than two years of pain post injury; baseline data was not provided.

Outcomes

All the studies measured pain using a Visual Analogue Scale (VAS). One also used a short form of the McGill Pain Questionnaire in addition to VAS (Gallagher 1994). Four studies used the Oswestry Disability Index (ODI) to measure disability (Tekin 2007, Lakemeier 2013, van Kleef 1999, Leclaire 2001) along with the Roland Morris Questionnaire (Lakemeier 2013, Leclaire 2001). Other outcomes included Global Perceived Effect (GPE) (van Kleef

1999, van Wijk 2005), Global Improvement Scale (Nath 2008) and the North American Pain Society patient satisfaction questionnaire (Civelek 2012). Two studies defined the success of treatment based on a combination of outcome variables: van Wijk (2005) used a reduction of median VAS-back of at least 50% without a drop in daily activities and/or reduction of at least 25% median VAS-back, with a simultaneous rise in daily activities of at least 25% and a drop in analgesic intake of at least 25%; and van Kleef (1999) used a two point reduction of pain and 50% pain reduction on GPE.

Diagnosis of Facet Joint Pain

The studies varied with regards to diagnosing facet joint pain (Table 3.2). Four studies used medical branch blocks with appropriate technique according to ISIS (Nath 2008, Tekin 2007, Lakemeier 2013, van Kleef 1999) while the other four used unclear or questionable techniques. (Civelek 2012, Gallagher 1994, Leclaire 2001, van Wijk 2005)

Only one study performed double blocks (Nath 2008) while another study cited legislative restraints as preventing them from performing controlled blocks (Tekin 2007). Single diagnostic medial branch blocks were used in six studies (Tekin 2007, Lakemeier 2013, van Kleef 1999, Gallagher 1994, Leclaire 2001, van Wijk 2005). One study did not describe how diagnostic blocks were performed (Civelek 2012).

The definition of a "successful block" was also different between studies varying from: 50% pain relief from baseline (Tekin 2007, Lakemeier 2013, van Kleef 1999, van Wijk 2005), >80% relief of pain (consistent with ISIS) (Nath 2008), 12 hours pain relief (Gallagher 1994) and 24 hours pain relief (Leclaire 2001). None of the studies reported whether the patients had restoration of movements following successful diagnostic blocks.

RFD technique

All the studies used an electrode temperature of 80^{o}C during the RFD procedure with the exception of Nath (2008) which used 85^{o}C. The duration of the heat varied from 60 seconds, (Nath 2008, van Kleef 1999, van Wijk 2005) 90 seconds (Tekin 2007, Lakemeier 2013, Gallagher 1994, Leclaire 2001) and 120 seconds (Civelek 2012). All studies except one (i.e. (Lakemeier 2013)) reported on how the electrodes were placed during the procedure. The number of lesions varied between the studies, with Nath (2008) making multiple lesions, Leclaire (2001) and Civelek (2012) only one. The remaining studies did not specifically report on how many lesions were made; although they were most probably single lesions, based on the information given in the studies. (see table 3.2)

Follow-up

The duration of follow up varied, from: three months (Leclaire 2001, van Wijk 2005), six months (Nath 2008, Lakemeier 2013, Gallagher 1994) and one year (Tekin 2007, van Kleef 1999, Civelek 2012).

Adverse effects

Adverse effects were reported in two studies (Civelek 2012, van Wijk 2005). Civelek (2012) reported receiving complaints of small superficial burns following RFD (no further information provided) that resolved after 6-8 weeks. The other study (van Wijk 2005) reported two patients in the RFD group having discrete loss of motor function (compared to one patient in the sham group) and one patient who underwent RFD reporting of dysaesthesia (no reports in sham group).

Risk of Bias

As most of the studies either did not adequately report their methods, their overall risk of bias was difficult to determine. Sequence generation was clearly reported in five (Nath 2008, Tekin 2007, Lakemeier 2013, Civelek 2012, van Wijk 2005), while concealment of allocation was only reported by two (Lakemeier 2013, Leclaire 2001). The majority of studies did not report whether patients, investigators or outcome assessors were blinded. Only one study took adequate measures to blind both the patients and the treating physician/surgeon (Leclaire 2001) and two studies blinded the outcome assessor (van Kleef 1999, Civelek 2012). Incomplete outcome data was accounted for in all studies as all patients were either followed up or intention to treat analysis was performed. There appeared to be no selective outcome reporting (see Table 5.1 and 5.4.1 of the Technical Report).

Although most of the studies reported no major baseline imbalances between groups, (Tekin 2007, Lakemeier 2013, Civelek 2012, Leclaire 2001, van Wijk 2005) one had more patients with longer duration of pain in the sham procedure group (median 48 versus 26 in RFD) (van Kleef 1999) and one had more patients with significant generalized, low back and referred pain to leg in the RFD group (Nath 2008).

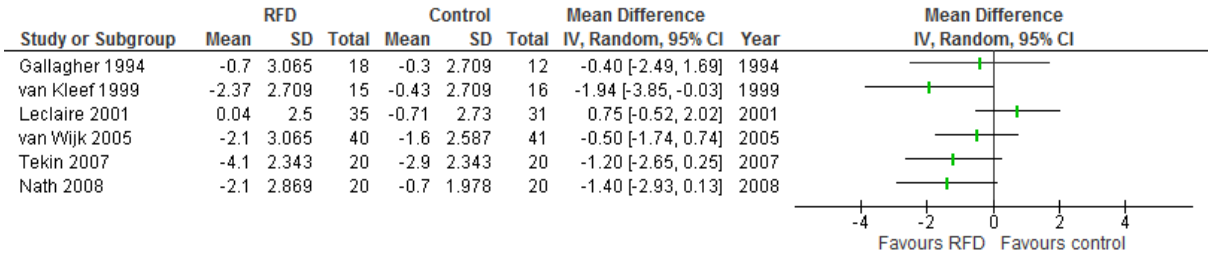
Results

RFD vs Sham

Pain

Out of the six studies that compared RFD against sham, only one study (van Kleef 1999) reported statistically significant reduction of back pain for RFD (VAS mean difference; -1.94 [95% CI -3.85 to -0.03]), while all others showed no significant difference. Although the study by Nath (2009) did not report a significant difference between groups for back pain, he did report significant improvements for generalized

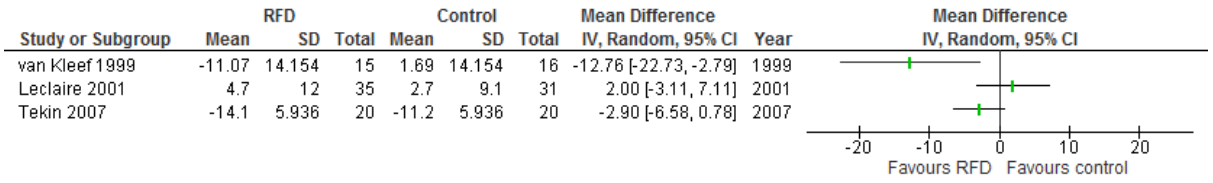
Figure 3.1 Meta-analysis RFD vs sham mean change pain scores in lumbar facet joint pain



Disability

Three studies (Tekin 2007, van Kleef 1999, Leclaire 2001) assessed disability using the ODI. Of these only one Van Kleef (1999) reported significant reduction in disability for RFD (mean difference; -12.76 [95% CI -22.73 to -2.79]), although the precision of this estimate is unclear given the wide confidence intervals.

Figure 3.2 Meta-analysis RFD vs sham mean change disability scores in lumbar facet joint pain

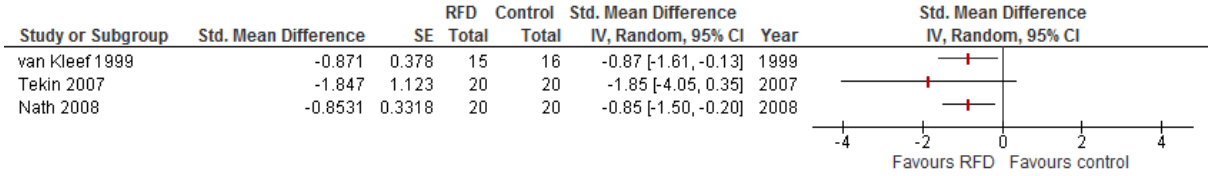


Study or Subgroup	RFD Mean	RFD SD	RFD Total	Control Mean	Control SD	Control Total	Mean Difference IV, Random, 95% CI	Year
van Kleef 1999	-11.07	14.154	15	1.69	14.154	16	-12.76 [-22.73, -2.79]	1999
Leclaire 2001	4.7	12	35	2.7	9.1	31	2.00 [-3.11, 7.11]	2001
Tekin 2007	-14.1	5.936	20	-11.2	5.936	20	-2.90 [-6.58, 0.78]	2007

Analgesic use

Three studies reported data on analgesic use (Nath 2008, Tekin 2007, van Kleef 1999) measured at different time points: 8 weeks (van Kleef 1999) 6 months (Nath 2008) and 12 months (Tekin 2007). Of these two reported a significant reduction in post procedure analgesic use in the RFD group while the other (Tekin 2007) reported no significant difference.

Figure 3.3 Meta-analysis RFD vs sham mean change analgesic use in lumbar facet joint pain

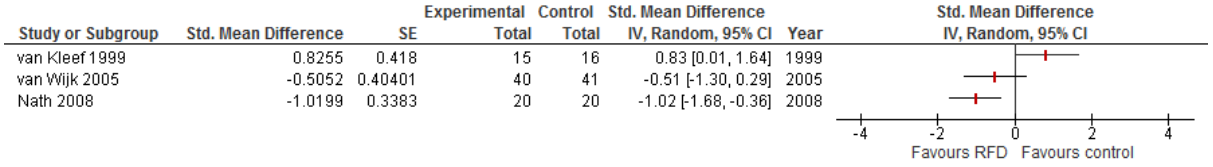


Study or Subgroup	Std. Mean Difference	SE	RFD Total	Control Total	Std. Mean Difference IV, Random, 95% CI	Year
van Kleef 1999	-0.871	0.378	15	16	-0.87 [-1.61, -0.13]	1999
Tekin 2007	-1.847	1.123	20	20	-1.85 [-4.05, 0.35]	2007
Nath 2008	-0.8531	0.3318	20	20	-0.85 [-1.50, -0.20]	2008

Global perceived effect

Three studies reported on patient rated measures (Nath 2008, van Kleef 1999, van Wijk 2005). Of these all reported different results with Nath (2008) reporting significant improvement for the RFD group, van Kleef (1999) favouring sham and van Wijk (2005) reporting no significant difference.

Figure 3.4 Meta-analysis RFD vs sham mean change global perceived effect in lumbar facet joint pain

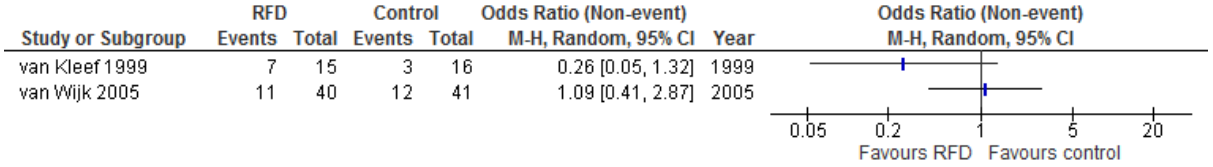


Study or Subgroup	Std. Mean Difference	SE	Experimental Total	Control Total	Std. Mean Difference IV, Random, 95% CI	Year
van Kleef 1999	0.8255	0.418	15	16	0.83 [0.01, 1.64]	1999
van Wijk 2005	-0.5052	0.40401	40	41	-0.51 [-1.30, 0.29]	2005
Nath 2008	-1.0199	0.3383	20	20	-1.02 [-1.68, -0.36]	2008

Successful outcome treatment

Two studies (van Kleef 1999, van Wijk 2005) reported on successful treatment based on predefined combined outcome measures and both failed to detect any significant difference between the RFD and sham procedure.

Figure 3.5 Meta-analysis RFD vs sham mean change successful treatment outcome in lumbar facet joint pain

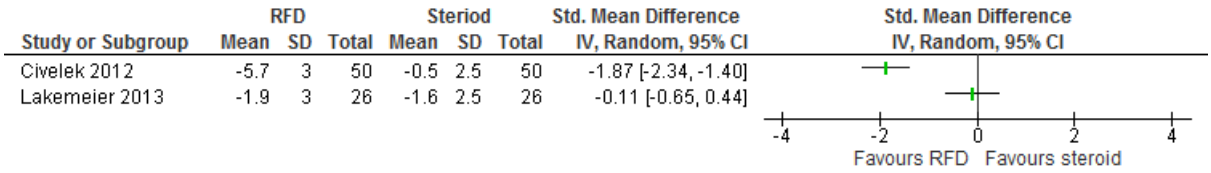


Study or Subgroup	RFD Events	RFD Total	Control Events	Control Total	Odds Ratio (Non-event) M-H, Random, 95% CI	Year
van Kleef 1999	7	15	3	16	0.26 [0.05, 1.32]	1999
van Wijk 2005	11	40	12	41	1.09 [0.41, 2.87]	2005

RFD vs Steroids

The two studies that compared RFD with steroid/local anaesthetic injections reported conflicting results for pain, with Civelek (2012) reporting significant pain reduction in the RFD group while Lakemeier (2013) reported no significant difference.

Figure 3.6 Meta-analysis RFD vs steroid mean change pain score in lumbar facet joint pain



Discussion

Even though the majority of studies show that RFD was no more effective than sham, these results are uncertain and may be affected by a number of factors, which are unique to each study. Using the GRADE rating, the evidence in support of RFD for lumbar facet joint pain was ranked low quality (Table 3.2 and 3.3), indicating that further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. This was also the case for the effect of RFD compared to steroids.

Unlike drug trials where study quality can be assessed using the standard risk of bias criteria, trials of medical procedures, such as RFD, present additional challenges in relation to internal validity. Specific to RFD two factors can affect the overall results: incorrect RFD technique and variation in the diagnosis of facet joint pain.

The ISIS guidelines recommend that patients whose facet joint pain has been adequately diagnosed should be targeted for RFD. (Bogduk 2014) To accurately diagnose facet joint pain, controlled diagnostic blocks are recommended. Among the eight studies, only Nath (2008) recruited patients whose facet joint pain was diagnosed using control blocks with 80% pain relief as a threshold for success.

However despite this, Nath's (2008) results for back pain were the same as those studies which used inadequate methods. Although Nath did report significant improvements in leg pain and generalized pain, this is probably explained by the fact that this study recruited patients with multiple sources of pain; where pain mediated by the lumbar medial branches was only one of several types of pain suffered.

Another important factor when interpreting the results is whether the studies used the correct technique for medial branch blocks. Of the studies included in this review at least three (Gallagher 1994, Leclaire 2001, van Wijk 2005) deviated from the technique recommended by the ISIS guidelines. (Bogduk 2014). Given this, it would be reasonable to expect the results of these studies to be different from the remaining studies, however the outcomes for back pain were not different from the studies that used methods consistent with the ISIS recommendations.

With regards to correct RFD technique only two studies conformed to the ISIS guidelines (Nath 2008, Tekin 2007) while another used a sub-optimal but acceptable technique (van

Kleef 1999) (Bogduk 2005). Despite this there was no significant difference between the studies that used an acceptable RFD technique (as per ISIS guidelines) and those that did not.

We also explored whether the studies reporting positive results were different to those that reported t. Overall one study reported improved results for back pain (van Kleef, 1999); one reported improved results for leg pain and generalized pain (Nath 2008), two studies reported disability improvements for RFD (Tekin 2007, van Kleef 1999) and two studies reported reduced analgesic use for RFD (Nath 2008, van Kleef 1999). With the exception of Nath (2008) we did not identify any key factors, which could explain this difference in results. We also explored whether time since injury had an impact on the overall results however no association was identified.

Overall it is difficult to interpret these studies as they each have unique limitations (despite reporting similar results), thus we cannot make any firm conclusion as to whether or not RFD is effective in improving facet joint pain and improving function.

Table 3.1. Key information from the synthesis of lumbar RFD RCT's presented in this report on RFD for lumbar facet joint

Effectiveness RFD on lumbar facet joint pain	We found very limited evidence supportive of the lumbar RFD. The overall effect is non-significant and the available studies suffer from methodological quality issues and use of questionable techniques.
Effect of RFD on function (functional status, psychological status, return to work and reduction in opioid intake)	Overall, the data indicate that RFD is no more effective than sham procedure in pain control and improving disability. There is very limited evidence to suggest that the RFD would reduce analgesic intake in patients, short term. Complications and adverse effects were not sufficiently reported to allow comparisons, and there was no evidence for cost-effectiveness.
Risks associated with RFD	Adverse effects were reported in two studies (Civelek 2012, van Wijk 2005). Civelek (2012) reported receiving complaints of small superficial burns following RFD (no further information provided) that resolved after 6-8 weeks. The other study (van Wijk 2005) reported two patients in the RFD group having discrete loss of motor function (compared to one patient in the sham group) and one patient who underwent RFD reporting of dysaesthesia (no reports in sham group).
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 effect of RFD in chronic lumbar facet joint pain is unclear.

	There is some controversy regarding procedural methodology and patient selection in addition to concerns regarding methodological bias in the included studies.
Recommendation category	Equivocal
Quality assessment results	Low quality studies

Table 3.2. Effects of patient selection and technique on outcomes

Study	Patient selection				Technique	Outcome		
	Pain duration before enrollment	Screening medial branch block	Control block	% of pain relief required from blocks	Electrodes placed accurately (Bogduk 2014)	Pain (mean difference in VAS)	Disability (mean difference)	Other outcomes
Gallagher 1994	>3 months as inclusion criterion No baseline data on group specific duration	Yes: Questionable technique Injection of 0.5%; 0.5ml bupivacaine was given into and around painful joint(s)	No	Not reported	Questionable technique (used the method described by Shealey CN)	At 6 months: RFD= -0.7 Sham= -0.3 [not significant]		
Van Kleef 1999	>12 months as inclusion criterion RFD=26 [12-120] months (median[range]) Sham=48 [12-192] months (median[range])	Yes: Acceptable technique Injection of 1%; 0.75ml Lidocaine directed at medial nerves	No	At least 50% on a four-point Likert scale	Sub-optimal technique (perpendicular placement of electrodes), nevertheless acceptable	At 2 months: RFD= -2.4 Sham= -0.4 Unadjusted: 1.94 (90% CI 0.24-3.64, p<0.05) [significant]	At 2 months: Oswestry Disability Index RFD=-11.07 Sham: 1.69 Unadjusted: 15.75 (90% CI 4.16-21.35, p<0.01) [significant]	Successful treatment outcomes At 2 months: Percentage of success RFD= 66.7 Sham= 37.5 Unadjusted: 3.33 (90% CI 0.97-11.5) [not significant] Global perceived effect RFD=1.33 Sham=0.37 Unadjusted: -0.96 (90% CI -1.70- -0.22) [significant p<0.05]

								Change in number of analgesic tablets per 4 days RFD=-2.13 Sham=1.75 Unadjusted: 3.88 (90 CI 1.19 - 6.57) [significant; p<0.05]
Leclaire 2001	>3 months as inclusion criterion No baseline data on group specific duration	Yes: Questionable technique Injection of 2%; 0.5ml Lidocaine and 0.5ml triamcinolone acetonide, intra-articular	No	Significant pain relief for at least 24 hours during the week	Questionable / unclear technique	At 3 months: RFD= 0.4 Sham= -7.1 [not significant]	At 3 months: Oswestry Disability Index RFD= -4.7 Sham= -2.7 [not significant]	
Van Wijk 2005	>6 months as inclusion criterion >2 years of pain RFD=77% Sham= 68%	Yes: Questionable technique Injection of 2%; 0.25-0.5ml of Lidocaine, intra-articular	No	At least 50% pain relief on a standard VAS after 30 minutes	Questionable technique (electrodes were placed away from target nerves-based on radiographic images provided)	At 3 months: Back pain (VAS) RFD= -2.1 Sham= -1.6 [not significant] VAS back reduction ≥2 points RFD=47.5% Sham= 48.8% [not significant] VAS back reduction ≥25% RFD= 62.5 Sham= 48.8	At 3 months: SF-36 physical functioning; mean difference & (SD) RFD= 4.7 (16.9) Sham= 7.8 (19.7) [not significant]	Successful treatment outcomes At 3 months: Defined using a combined outcome measure RFD=27.5% Sham= 29.3% [not significant] Global perceived effect for back pain (>50% pain relief) RFD=61.5% Sham=39.0% [significant; OR 2.5

						[not significant]		(1.0-6.1) p=0.044]
Tekin 2007	>6 months as inclusion criterion RFD=37.5 ±12.4 months Sham= 32.8 ± 11.2 months	Yes: Acceptable technique Injection of 2%; 0.3ml of Lidocaine at medial branch roots	No	At least 50% pain relief on a standard VAS	Acceptable technique	At 6 months: RFD= -4.2 Sham= -3.7 [not significant]	At 6 months: Oswestry Disability Index RFD= -14.1 Sham= -11.2 [significant; P<0.05]	At 12 months: Patients using analgesics (point estimate) RFD=40% Sham= 95%
Nath 2008	≥2 years as inclusion criterion No baseline data on group specific duration	Yes: Acceptable technique Injection of 0.5%; 1ml of bupivacaine at medial branch	Yes: Control blocks using lidocaine and bupivacaine	At least 80% pain relief	Acceptable technique	At 6 months: Back pain: RFD=-2.1 Sham= -0.7 [not significant] Generalized pain: RFD=-1.93 Sham=-0.38 [significant; p=0.02] Leg pain: RFD=-1.6 Sham=-0.13 [significant; p=0.046]		At 6 months: Patients using analgesics (mean difference) RFD=-1.40 Sham=-0.60 [significant; p=0.04]
Civelek 2012	RFD=18.9±12.9 months Facet joint injections (FJI) =18.7±12.3 months	No test blocks	No	Not relevant	Questionable technique	At 6 months: RFD=-5.7 FJI=-4.1 [significant; p<0.001]		

Lakemeier 2013	≥2 years as inclusion criterion No baseline data on group specific duration	Yes: Insufficient information Injection of 0.5%; 0.5ml of bupivacaine	No	At least 50% pain relief	Inadequate description of technique	At 6 months: RFD=-1.6 FJI=-1.9 [not significant; p=0.60]	At 6 months: Oswestry disability Index RFD=-5.7 FJI=-12.8 [not significant; p=0.06]	

Table 3.3. Summary of findings table for lumbar facet joints (RFD vs sham)

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk **Placebo**	Corresponding risk **Radiofrequency**				
Visual Analog Scale 0-10 scale Follow-up: 2 to 6 months	The mean visual analog scale ranged across control groups from **-3.7 to -0.3 units**[1]	The mean visual analog scale in the intervention groups was **0.55 lower** (1.33 lower to 0.22 higher)		288 (6 studies)	⊕⊕⊖⊖ **low**[2,3]	
Oswestry Disability Index 0-100% scale Follow-up: 2 to 6 months	The mean oswestry disability index ranged across control groups from **1.69 to -11.2 units**[1]	The mean oswestry disability index in the intervention groups was **0.75 lower** (10.49 lower to 8.99 higher)		137 (3 studies)	⊕⊕⊖⊖ **low**[2,3]	
Analgesic Use Follow-up: 2 to 6 months	The mean analgesic use ranged across control groups from **0.33 to 1.12 standard error**[1,4]	The mean analgesic use in the intervention groups was **0.91 standard deviations lower** (1.38 to 0.43 lower)		111 (3 studies)	⊕⊕⊖⊖ **low**[2,3]	
Global Perceived Effect Follow-up: 2 to 6 months	The mean global perceived effect ranged across control groups from **0.34 to 1.12 standard error**[1,4]	The mean global perceived effect in the intervention groups was **0.01 standard deviations higher** (1.44 lower to 1.46 higher)		152 (3 studies)	⊕⊕⊖⊖ **low**[2,3]	
Successful Treatment Outcome Y/N Follow-up: 2 to 3 months	**Study population**		**OR 1.60** (0.41 to 6.23)	112 (2 studies)	⊕⊕⊖⊖ **low**[2,3]	
	263 per 1000	**364 per 1000** (128 to 690)				
	Moderate					

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).
CI: Confidence interval; **OR:** Odds ratio;

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] Mean change score.
[2] Methodological concerns on patient selection and placement of probes.

[3] All the studies had small sample size (ranging from 30 to 81). Five out of the 6 studies had 95% CI that includes no effect.
[4] All 3 studies used different units of measurement. Thus the standardized mean difference was used to compare the studies and the standard error was reported as the possible change score in controls.

Table 3.4. Summary of findings table for lumbar facet joints (RFD vs steroid)

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk **Steroid**	Corresponding risk **Radiofrequency denervation**				
Visual numeric/analog scale 0-10 scale Follow-up: mean 6 months	The mean visual numeric/analog scale ranged across control groups from **4.4 to 5.4 units**	The mean visual numeric/analog scale in the intervention groups was **1.33 lower** (2.51 to 0.16 lower)		152 (2 studies)	⊕⊕⊖⊖ **low**[1,2]	

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval;

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] Methodological concerns for incorrect patient selection and incorrect placement of probes.
[2] Small sample size and huge 95% CI range.

4. SACROILIAC JOINTS

Evidence Identified

Two systematic reviews (Hansen 2012, Aydin 2010) were identified which evaluated RFD on sacroiliac joint pain. The review by Hansen (2012) evaluated different types of therapeutic interventions such as intra-articular injections, peri-articular injections, conventional RFD, cooled-probed RFD and pulsed RFD. The review by Aydin (2010) evaluated the role of RFD for sacroiliac joint pain. After comparing these reviews we chose to access Hansen (2012) as it was the most comprehensive, with a low risk of bias (see Table A5.5 of the Technical Report).

Characteristics of the Included Studies

The review by Hansen (2012) included two RCTs (Cohen 2008, Patel 2012) which evaluated the effect of RFD on sacroiliac joint pain. Both studies were conducted in USA and used cooled-probed RFD as the therapeutic intervention.

In Cohen (2008), 28 patients were recruited: 14 patients received L4-5 primary dorsal rami and S1-3 lateral branch RFD using cooled-probe technology followed with a local anaesthetic block and 14 patients received the local anaesthetic block followed by placebo denervation. Patients were screened by a single diagnostic sacroiliac joint injection and only patients who experienced ≥ 75% pain relief as calculated from a 6-hour post-block pain diary were included in the study. Patients were followed up for 1, 3 and 6 months post intervention. The primary outcome measure was a 0–10 Numeric Rating Scale (NRS) pain score. Secondary outcome measures included the Oswestry Disability Index (ODI) score, reduction in analgesic medications (defined as a 20% reduction in opioid use or complete cessation of a non-opioid analgesic), global perceived effect (GPE), and a composite score for successful outcome. The composite binary variable “successful outcome” was pre-defined prior to initiation of the study as a ≥ 50% reduction in numerical pain score, a positive GPE, and either a 10-point decrease in ODI or a 4-point decrease coupled with a reduction in medication usage. Further details of the study’s characteristics can be found in the Technical Report, Table A4.4.1.

In Patel (2012), patients were screened with two sets of anaesthetic blocks where a positive response was defined as ≥75% pain relief for between 4 hours and 7 days following the injections. This blocking protocol was repeated on a separate day, after a return to baseline pain. Subjects achieving 75% relief of their index pain after both blocks were required to return to baseline pain before entry into the study. A total of 51 patients were randomized on a 2:1 basis to RFD and sham groups, respectively. Pain, physical function, disability, GPE and quality of life were measured at 1, 3, 6, and 9 months post intervention. A NRS was used to assess pain. The ODI was used to assess disability. The Short Form SF-36 (version 1) was used to assess bodily pain and physical function using the respective subscales: SF-36BP and SF-36PF. Quality of life was measured using the Assessment of Quality of Life (AQoL) assessment tool. GPE was measured by having subjects rate their index pain on a 7-item scale. Further details of the study’s characteristics can be found in the Technical Report, Table A4.4.2.

Quality of the Included Studies

Both studies had low risk of bias with adequate methods of randomization, concealment of treatment allocation, blinding of patients and outcome assessors, similar groups at baseline, adequate reporting and intention to treat analysis. The only parameter, which was not met by the studies, was that the investigators were unblinded. We also assessed the quality of the evidence according to the GRADE system and scored them to be of moderate quality (Technical Report, Table A7.4).

We assessed the risk of bias for the review by Hansen (2012) and determined the risk to be low. We also mapped the 2 RCTs to the critical criteria for the optimal conduct of RFD (Bogduk 2005), with the exception of the procedure, as cooled radiofrequency denervation requires that the probes are placed perpendicular rather than in a parallel trajectory.

One of the key criteria for diagnosing facet joint pain, according to the ISIS guidelines (Bogduk 2014), is the use of controlled blocks as method of minimizing false positives during patient selection. This was done in Patel (2012) but not in Cohen (2008). With regards to the RFD techniques the electrodes were placed using a perpendicular rather than parallel trajectory in both studies.

Results

Pain

We conducted a meta-analysis based on the two RCTs for the following outcomes: pain, function and successful treatment (see Fig 4.1-4.4). Using the method by Fu (2013), the mean change scores were calculated by subtracting the mean scores of the follow-up period from the baseline, so as to better compare the effect of the intervention. The standard deviations of the mean change score from Patel (2012) were reported directly from the study. The standard deviations of the mean change score from Cohen (2008) were imputed from Patel (2012) since it was not reported and no other statistics (such as p value or 95% CI) were given for direct calculation.

Overall, both studies showed significant improvements for RFD compared to sham in treatment success at 3 months but only Patel (2012) showed significant improvement in pain score at 3 months.

Figure 4.1 Meta-analysis RFD vs sham mean change pain score in sacroiliac facet joint pain at 3 months

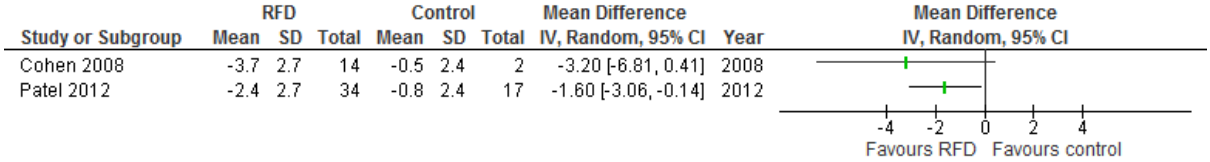
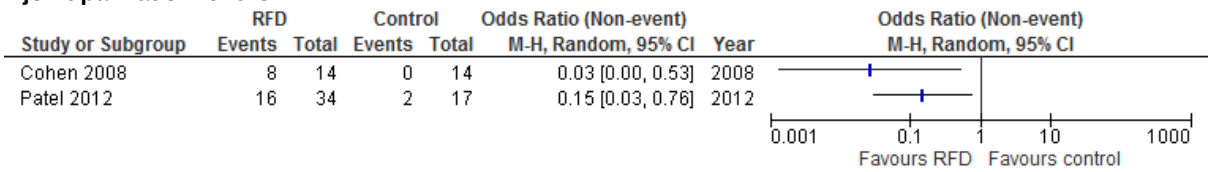


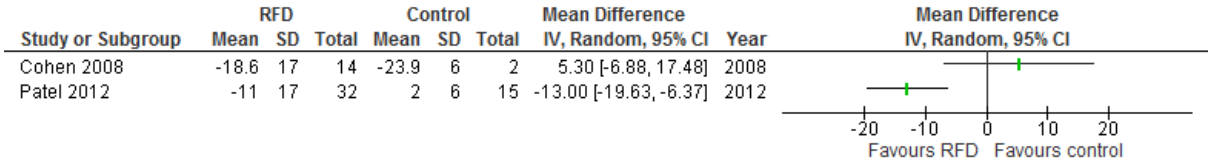
Figure 4.2 Meta-analysis RFD vs sham mean change successful treatment outcome in sacroiliac facet joint pain at 3 months



Disability

Both of the studies produced conflicting results in terms of improvement in disability with Patel (2012) showing significant improvement in the RFD group while Cohen (2008) showed improvement in the sham group.

Figure 4.3 Meta-analysis RFD vs sham mean change disability score in sacroiliac facet joint pain at 3 months



Discussion

Although moderate quality evidence was identified, the effect of RFD on sacroiliac pain is not definitive. Despite showing some level of improvements for RFD in pain and treatment success, this was not observed for disability. Furthermore there may be differences in the patients recruited for each of the studies as Patel (2012) performed controlled blocks for diagnosing sacroiliac pain while Cohen (2008) used only single blocks (Table 4.2), which could potentially produce false positive results. If the source of pain in the Cohen (2008) cohort was not attributed to sacroiliac facet joint then it is understandable that RFD would not be any more effective than sham, which what was observed for the pain and disability outcomes.

Table 4.1. Key information from most up-to-date, high quality synthesised study for sacroiliac joint

Hans Hansen, MD, Laxmaiah Manchikanti, MD, Thomas T. Simopoulos, MD, Paul J. Christo, MD, Sanjeeva Gupta, MD, Howard S. Smith, MD, Haroon Hameed, MD, and Steven P. Cohen, MD. A Systematic Evaluation of the Therapeutic Effectiveness of Sacroiliac Joint Interventions. Pain physician. 2012;15;E247-E278.	
Study design	Systematic Review
Scope	**Patient/population:** people with sacroiliac joint pain (systematic review of 11 studies – 6 RCTs and 5 non-randomised studies; out of the 6 RCTs, 2 met our inclusion criteria which used cooled-probe RFD neurotomy) **Conditions indicated for use:** sacroiliac joint pain **Intervention:** diagnostic and therapeutic interventions (including intra-articular and peri-articular sacroiliac joint injections and radiofrequency neurotomy of the nerve supply of the sacroiliac joint) **Outcomes assessed:** pain relief (short-term relief = up to 6 months and long-term = > 6 months); secondary outcomes were improvement in functional status, psychological status, return to work and reduction in opioid intake.
Effectiveness RFD on sacroiliac joint pain	This review found fair evidence for the effectiveness of cooled-probed RFD neurotomy.
Effect of RFD on function (functional status, psychological status, return to work and reduction in opioid intake)	Although the review set out to look at some of these outcomes, only results from pain and function were discussed.
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 evidence for cooled-probe RFD neurotomy in managing sacroiliac joint pain is fair based on 2 randomized, double-blind placebo-controlled trials”.
Recommendation category	Positive
Quality assessment results	Low risk of bias

Table 4.2. Effects of patient selection and technique on outcomes

Study	Patient selection				Technique	Outcome		
	Pain duration before enrollment	Screening medial branch block	Control block	% of pain relief required for blocks	Electrodes placed accurately (Bogduk 2014)	Pain	Disability	Successful treatment outcome
Cohen 2008	> 6 months	Yes: Questionable technique Sacroiliac joint injections of 2ml bupivacaine 0.5% into the bottom one-third of the joint	No	≥75%	Yes	-3.2 (3-month change score between groups); not significant	5.3 (3 month change score between groups); not significant	5.3 (6-month change score between groups); not significant
Patel 2012	> 6 months	Yes: Acceptable technique 0.5cc of 0.5% bupivacaine injected according to ISIS guidelines	Yes	≥75%	Yes	-1.6 (3-month change score between groups); p=0.035	-13 (3-month change score between groups); p=0.011	-13.0 (3-month change score between groups); p<0.05

Table 4.3. Summary of findings table for sacroiliac facet joints

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk **Placebo**	Corresponding risk **Radiofrequency denervation**				
Numeric Rating Scale 0-10 scale Follow-up: mean 3 months	The mean numeric rating scale ranged across control groups from **-0.5 to -0.8 units**[1]	The mean numeric rating scale in the intervention groups was **1.81 lower** (3.17 to 0.45 lower)		67 (2 studies)	⊕⊕⊕⊖ **moderate**[2]	
Oswestry Disability Index 0-100% scale Follow-up: mean 3 months	The mean Oswestry Disability Index ranged across control groups from **2 to -23.9 %**[1]	The mean Oswestry Disability Index in the intervention groups was **7.02 lower** (23.84 lower to 9.80 higher)		63 (2 studies)	⊕⊕⊕⊖ **moderate**[2]	
Successful Treatment Outcome Y/N Follow-up: 3 to 6 months	**Study population** **65 per 1000**	**407 per 1000** (139 to 744)	**OR 9.95** (2.34 to 42.24)	79 (2 studies)	⊕⊕⊕⊖ **moderate**[2]	

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **OR:** Odds ratio;

GRADE Working Group grades of evidence
High quality: Further research is very unlikely to change our confidence in the estimate of effect.
Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.
Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.
Very low quality: We are very uncertain about the estimate.

[1] Mean change score
[2] Small sample size and Cohen 2008 paper has a huge 95% CI range.

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.

A key finding of this review is the inconsistency in the findings of primary studies and in the conclusions drawn by authors. Some RCTs report that RFD is effective, while others report inconclusive results or find no effect.

Furthermore procedural trials are further challenged by internal validity. In this case any deviation from the correct RFD technique will result in incorrect results and thus conclusions. Furthermore variations in how facet joint pain is diagnosed using diagnostic blocks can also increase the likelihood of a false diagnosis and affect the outcomes of the studies.

RFD for persistent pain of cervical facet joint origin:

Based on one small RCT (Lord 1996) there is moderate level evidence to support the use of RFD for cervical facet joint pain.

RFD for persistent pain of thoracic facet joint origin:

The most up-to-date systematic review (Manchikanti 2012) on treatment options for thoracic facet joint pain was unable to identify any comparative studies on the effect of radiofrequency (AA) denervation vs sham. The only available RCT evaluates RFD compared to alcohol ablation which is of limited clinical utility given that AA is not recommended for non cancer pain.

RFD for persistent pain of lumbar facet joint origin:

Only low quality evidence exists for RFD for lumbar facet joint pain. All of these however had 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:

The most recent high-quality synthesised source of evidence (Hansen 2012) was based on two small moderate quality RCT's however these presented conflicting results and thus no specific conclusions about whether or not RFD is effective for sacroiliac facet joint pain.

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/VWA 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/VWA Health and Disability Strategy 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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