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Original Article

Lumbar facet joint injection in treating low back pain: Radiofrequency denervation versus SHAM procedure. Systematic review

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ABSTRACT

The lumbar facet joints have been implicated as one of the causes of low-back pain syndromes. About 15–40% of patients who presented with chronic low-back pain was attributed to lumbar facet joint pain. The purpose of this study was to analyse whether radiofrequency denervation is better than SHAM procedure in treating chronic low-back pain caused by lumbar zygapophysial joints pathology. From the four identified randomised control trials, there is conflicting evidence at an intermediate 3–6-month stage, however; one study demonstrates statistical significance of radiofrequency denervation at 3 months. Longer-term follow-up is needed to prove the efficacy of radiofrequency denervation technique.

1. Introduction

Acute low back pain is one of the most common causes of generalised pain [1] with majority of the adult population experiencing an acute episode at some stage of their lives.[2] A specific cause is only found in a few patients [3] and often, symptoms tend to resolve in the majority of patients without any specific treatment. However, in about 8–12% of patients, chronic low back pain develops and becomes a major source of disability.[2,4]

The lumbar facet joints have been implicated as one of the causes of low back pain syndromes.[5–7]About 15–40% of patients who presented with chronic low back pain were attributed to lumbar facet joint pain.[8,9]The source of innervation of the lumbar facet joints is by the medial branches of the dorsal ramus and has been described briefly by Bogduk and Long.[10–12] In 1975, Shealy published his first paper describing a technique for radiofrequency localization and coagulation of articular nerves supplying spinal facets.[13] Since then, his technique has been modified and used with varying results of success.[14–17] The aim for neurotomy is based on the premise that cutting the nerve supply to a painful structure may relief pain and subsequently permits a return of function. There are two essential criteria that determine treatment success. Firstly, the structures responsible for the pain, at or near the articular facets joints must be identified by use of a diagnostic block.[18–23] Secondly, the precise location and section of the nerve supply to that joint must be identified [12, 24,25]

The aim of this study was to conduct a rigorous scientific evaluation of the available randomised controlled trials and provide evidence to compare the outcome of radiofrequency denervation compared to sham or placebo procedures for the treatment of chronic low back pain caused by lumber zygapophysial (facet) joint pathology.

2. Methods

2.1. Study design and objectives

This is a systematic review of randomised control trials comparing outcomes of radiofrequency denervation versus sham treatment of the lumbar facet joints as a treatment modality for chronic low back pain.

2.2. Search strategy for relevant studies

We sought randomised control trials that compared radiofrequency denervation to placebo treatment for low back pain. We performed an electronic search on the 10th August 2016 using the Ovid Medline, EMBASE and PubMed databases to identify relevant articles. The search criteria were restricted to “Randomized Controlled Trial”. For the Medical Subject Heading (MeSH) term “Low Back Pain” and “radiofrequency” were used, with “surgical” as the subheading. Articles were restricted to the English language and limited to the most recent articles published between January 2000 up to the current date.

2.3. Inclusion criteria

Two reviewers (M.A.; R.S.) independently selected the trials that were included in the review. The title, key words and abstracts were reviewed to determine if the study met the inclusion criteria. Papers

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were considered for review if they satisfied all the following inclusion criteria: They were original articles on the treatment of chronic low back pain caused by facet joint osteoarthritis. In adult patients above 17 years of age and including both genders. Continuous low back pain with or without radiating pain for more than 6 months with focal tenderness over the facet joints. The articles described treatment consisting exclusively of RCTs comparing radiofrequency neurotomy versus placebo/sham procedure as the primary study. Reported at least 1 of the following primary or secondary outcomes of interest: global perception of improvement; improvement of back and leg pain; range of motion of the lumbar spine; hip movement; quality of life variables or clinical signs and rates of complication. Articles published after January 2000 and limited to English language.

The report quality was assessed using a checklist for the consolidated standards of Reporting Trials (CONSORT).[26]

2.4. Exclusion criteria

The following articles were excluded: non-randomized controlled trials, any study performed before January 2000, articles not published in English language, studies carried out for patients which are confined to an age group which is below 17 years of age and pain duration for less than six months. Studies carried out that included patients with prior radiofrequency denervation treatments, coagulopathies, malignancy, infections, mental handicap, psychiatric disorders, motor deficits or any other indications for surgical treatment were excluded. All experimental studies and studies comparing radiofrequency neurotomy with other methods for treating facets joints osteoarthritis were also excluded.

3. Results

3.1. Study identification and selection

Four papers were identified from using the above search criteria, proved to be eligible for the study and were concordant with our criteria [27–30]

1. Leclaire R, Fortin L, Lambert R, Bergeron YM, Rossignol M. Radiofrequency facet joint denervation in the treatment of low back pain: a placebo-controlled clinical trial to assess efficacy. Spine (Phila Pa 1976). 2001;26(13):1411-6; discussion 7.
2. Geurts JW, van Wijk RM, Wynne HJ, Hammink E, Buskens E, Lousberg R, et al. Radiofrequency lesioning of dorsal root ganglia for chronic lumbosacral radicular pain: a randomised, double-blind, controlled trial. Lancet. 2003;361(935)1:21-6.
3. van Wijk RM, Geurts JW, Wynne HJ, Hammink E, Buskens E, Lousberg R, et al. Radiofrequency denervation of lumbar facet joints in the treatment of chronic low back pain: a randomized, double-blind, sham lesion-controlled trial. Clin J Pain. 2005;21(4):335-44.
4. Nath S, Nath CA, Pettersson K. Percutaneous lumbar zygapophysial (Facet) joint neurotomy using radiofrequency current, in the management of chronic low back pain: a randomized double-blind trial. Spine (Phila Pa 1976). 2008;33(12):1291-7.

3.2. Description of included studies

The study characteristics have been described in the table below (Table 1). 3 of the identified studies were conducted in Europe, whilst one was conducted in Canada. All studies were double-blinded. Investigators included adult patients who presented with symptoms of lumbosacral back pain of varying duration. Leclaire et al.[27] included 70 patients with low back pain of a minimum of 3 months duration. Both Geurts et al. [28] and Van Wijk et al.[29] included 83 and 81 patients respectively with symptomatic low back pain for 6 months duration, whilst Nath et al.[30] included a smaller cohort of patients (40 patient) but longer duration of symptoms (2 years) (Table 2).

All patients included in the studies were deemed to have a positive response i.e. relief of low back pain after an intraarticular facet joint injection performed under fluoroscopic guidance. Both Geurts et al. and Nath et al. performed this diagnostic nerve block on 3 and 2 separate occasions respectively prior to patients being included in the trial. Leclaire et al. and Van Wijk et al. performed this diagnostic block on a single occasion. Methods for randomisation of patients into treatment of sham groups was deemed adequate in all studies with use of pre-assigned closed envelopes or a computer-generated randomization schedule. Apart from the study performed by Geurts et al., all other studies had an equal distribution of patient between the treatment and control groups.

3.3. Nature of radiofrequency technique

The surgical interventions have been well described in all four studies. Following appropriate identification of the medial branch of the distal portion of the spinal posterior rami using both stimulation at 5 Hz with a 0.5 msec pulse and regional anaesthesia, Leclaire et al. raised the temperature of the electrode tip to 80 °C for 90 s. A 22G electrode with a 5-mm exposed tip was utilised. Two neurotomies were performed (at the proximal and distal portions of the articular facet nerve) at a minimum of two levels (L4-L5 and L5-S1 unilaterally on the painful side or bilaterally). This was a pre-determined level based on the initial facet injection. The sham group underwent the same procedure, but the temperature of the tip was maintained at 37 °C.

Geurts et al. placed a 22G, 5 mm active-tip electrode in the dorsal-cranial quadrant of the intervertebral foramen and advanced the tip between a third and halfway into the pedicle column at a lumbar level. The technique had to be modified at sacral level, with use of a smaller 4 mm electrode tip. A sensory stimulation of 50 Hz and motor stimulation of 2 Hz was required to identify the root ganglion. The location of the dorsal root ganglion was confirmed by injecting iohexol and mepivacaine to produce dermatomal anaesthesia. The electrode was heated to a lesser temperature (67 °C), but an equivalent duration of 90 s. For the control group, no radiofrequency current was passed.

Van Wijk et al. performed a similar technique to Geurts et al. to identify the dorsal root ganglion using sensory and motor stimulation applied at 50 Hz and 2 Hz. A 22G electrode size was again utilised. 5 mL of 2% mepivacaine was subsequently injected through each electrode to obtain local anaesthesia. Electrodes were heated to 80 °C for 60 s in the treatment group but maintained in position without switching on the RF current in the control group.

Nath et al. confirmed the position of the tip of the electrode using four C-arm (tunnel, postero-lateral, cephalad and lateral) views. They injected 2mls of 5% bupivacaine to anaesthetise the target nerve and produce dermatomal anaesthesia. A 22G electrode size was utilised. A thermistor probe was inserted, and a 60 s lesion at 85 °C was performed. Another lesion was created 5 mm posterior to the initial lesion with a further 4 lesions medial and lateral to the initial two lesions to account for variations in location of the target nerve.

3.4. Analysis of primary and secondary outcome measures

All four studies used the visual analogue score (VAS) as one of their primary outcome criteria (POC). The VAS varied between measurements of generalised pain (VAS-GP), back pain (VAS-BP), leg pain (VAS-LP) or all the above.

Leclaire et al. utilised VAS-GP on a scale of 0–100. Baseline values on enrolment were similar at 51.9U for the treatment group and 51.5U for the placebo group. At 4 weeks for the treatment group, the VAS-GP improved by 3.6U, but at 3 months, pain was deemed worse by 0.5U. For the placebo group, pain was worse at 4 weeks with an increase of 0.6U, but at 3 months, pain had improved with a VAS-GP reduction by of 7.2U. Statistical analysis showed no significant difference between

Table 1
Comparison of study settings, participants, interventions and outcome measures used

	Leclaire (27)	Geurts (28)	Van Wijk (29)	Nath (30)
Design	Double-blinded RCT	Double-blinded RCT	Double-blinded RCT	Double-blinded RCT
Year published	2001	2003	2005	2008
Location	Canada	Netherlands	Netherlands	Sweden
Total number screened	Not mentioned	1001	462	376
Total number eligible	70	83	81	40
Randomisation methods	Use of four sets of closed envelopes	Use of four sets of closed envelopes	Use of four sets of closed envelopes	Computer-generated randomization schedule.
RF Group	36	45	40	20
Control Group	34	38	41	20
Age range (SD) − RF	46.7 (9.3)	46.9 (11.5)	46.9 (11.5)	56 (36–79)
Age range (SD) − control	46.4 (9.8)	45.3 (11.0)	48.1 (12.6)	53 (37–76)
Gender (M:F) − RF	12:24	18:27	10:30	6:14
Gender (M:F) − control	13:21	15:23	12:28	9:11
Inclusion criteria	Low back pain lasting more than 3 months' duration	Lumbosacral back pain lasting > 6 months	Duration of pain − 6 months	Continuous low back pain of at least 2 years' duration
	Good response after intraarticular facet injections under fluoroscopy	Pain relief after 3 separate, single-level, diagnostic nerve blocks under fluoroscopic guidance	> 50% Visual Analog Scale (VAS) reduction on diagnostic block under fluoroscopic guidance	2 separate positive facet blocks.
Intervention	RF group was treated with a 90 s RF lesion at temp of80 °C of the medial branch of distal	RF group was treated with a 90 s RF lesion at temp of 67 °C.	RF group was treated with a 60 s RF lesion at temp of 80 °C.	RF group was treated with a 60 s RF lesion at temp of85 °C. Cannula withdrawn 5 mm and another lesion made. 4 more lesions medial and lateral to first 2 lesions made.
	portion of the spinal posterior rami nerve	In the control group, electrodes were positioned in a similar position to the RF group, but no radiofrequency current was passed.	In the control group, electrodes and thermocouple probes were positioned similar to RF group, but without switching on the RF current	In sham group, electrodes were introduced as in (RF group), but electrode maintained at body temperature.
	In sham group, electrodes were introduced as in (RF group), but the temperature maintained at 37 °C			
Primary outcome measure	Functional disability (Roland Morris score + Oswestry)	Visual analogue (VAS) leg-pain and back-pain scores	Combined outcome measure	Global perception of improvement *(patients own subjective assessment on a 6-point scale)*
	Pain levels (VAS)	Physical impairment Analgesic intake	Pain levels (VAS) Physical activities Analgesic intake	Pain levels (VAS)
Secondary outcome measure	Tri-axial dynamometry of low back mobility	SF-36 (*Quality of Life Questionnaire)*	Global perceived effect *(complete relief, > 50% relief, no effect, pain increase)*	Motion of the lumbar spine, hip movement
	Maximal strength against resistance	Pain intensity		Quality of life variable *(6-point scale)*
	B-200 (angular speed against 25% of the maximum strength resistance)	Physical activities scale	SF-36 (*Quality of Life Questionnaire)*	Clinical signs *(present or absent)*
Time to primary outcome measure	4 weeks 12 weeks	3 months	3 months	6 months

Table 2
Comparison of primary and selective secondary outcome measures.

	Leclaire (27)	Geurts (28)	Van Wijk (29)	Nath (30)
Primary outcome measure:	Functional disability (Roland Morris score + Oswestry)	Visual analogue (VAS) leg-pain and back-pain scores	Pain levels (VAS)	Global perception of improvement *(patients own subjective assessment on a 6-point scale)*
	Pain levels (VAS)	Physical impairment Analgesic intake	Physical activities Analgesic intake	Pain levels (VAS)
Time to primary outcome measure	4 weeks 3 months	3 months	3 months	6 months
Combined outcome measure (comprising of VAS, physical activities, and analgesic intake, from a twice- weekly recorded diary)	NA	NA	Success defined by COM in RF group – 27.5% Success defined by COM in control group – 29.3% Difference in success (p = 0.86)	NA
Visual analogue scale	VAS: (0–100)	VAS: (0–10)	VAS: (0–10)	VAS: (0–10)
VAS Generalised Pain (VAS-GP)	(RF group) Baseline VAS-GP: 51.9 U Generalised pain reduced by 3.6 U at 4 weeks and increased by 0.5 U at 3 months (Control Group) Baseline VAS-GP: 51.5 U Generalised pain increased by 0.6 U at 4 weeks and reduced by 7.2 U at 12 weeks 4.2% change at 4 weeks −7.6% change at 12 weeks. No significant difference in treatment effect between two groups	NA	NA	(RF Group) Baseline VAS-GP: 6.03 U Generalised pain reduced by 1.9 U on 11-point scale *(p = 0.002)* (Control Group) Baseline VAS-GP: 4.10 U Generalised pain reduced in control group by 0.4 U on 11-point scale *(p = 0.29)* Difference in reduction – 1.55 U *(p = 0.02)*
VAS Back Pain (VAS-BP)	NA	(RF Group) Baseline VAS-BP: 5.8 U Back pain reduced 0.6U (Control Group) Baseline VAS-BP: 6.2 U Back pain reduced 1.1 U Difference in reduction – *(p = 0.32)*	(RF Group Baseline VAS-BP: 5.8 U Back pain reduced 2.1 U *(p = 0.0001)** (Control Group) Baseline VAS-BP: 6.5 U Back pain reduced by 1.6 U *(p = 0.0003)**	(RF Group) Baseline VAS-BP: 5.98 U Back pain reduced by 2.1 U *(p = 0.004)** (Control Group) Baseline VAS-BP: 3.88 U Back pain reduced by 0.7 U *(p = 0.13)* Difference in reduction – *(p = 0.004)**
VAS Leg Pain (VAS-LP)	NA	(RF Group) Baseline VAS-LP: 6.1 U Leg pain reduced by 0.7U *(p = 0.02)* (Control Group) Baseline VAS-LP: 6.2 U Leg pain reduced in control group by 2.0 U Difference in reduction – *(p = 0.02)*	(RF Group) Baseline VAS-LP: 4.2 U Leg pain reduced by 1.1 U *(p = 0.0059)** (Control Group) Baseline VAS-LP: 4.1 U Leg pain reduced in control group by 0.7 U	(RF Group) Baseline VAS-LP: 4.33 U Referred leg pain reduced by 1.6 U (p = 0.016) (Control Group) Baseline VAS-LP: 2.73 U Referred leg pain reduced by 0.13 U *(p = 0.31)* Difference in reduction – *(p = 0.004)**
Analgesia intake	Analysis of medications (acetaminophen or NSAIDs) or non-pharmacological treatment showed no significant difference between the two groups at 4 or 12 weeks follow up.	(RF Group) Baseline consumption (8-point scale): 1.4 U Analgesic requirement was reduced by 0.1 U (Control Group)	(RF Group) Baseline consumption (8-point scale): 1 U Analgesic requirement was reduced by 0.1 U (Control Group)	(RF Group) Baseline consumption (6-point scale): 4.33 U Analgesic requirement was reduced by 1.4 U *(p = 0.001)* (Control Group)

(*continued on next page*)

Table 2 (*continued*)

	Leclaire (27)	Geurts (28)	Van Wijk (29)	Nath (30)
		Baseline consumption (8-point scale): 1.3 U Control group – analgesic requirement was reduced by 0.2 U No statistical significance found between groups (p = 0.23)	Baseline consumption (8-point scale): 1.5 U Control group – analgesic requirement was reduced by 0.2 U No statistical significance found between groups	Baseline consumption (6-point scale): 3.80 U Analgesic requirement was reduced by 0.6 U *(p = 0.024)* Difference between groups –(p = 0.04)*
Oswestry Score (OS)	(RF group) Baseline OS: 38.3 Improved by 2.7% at 4 weeks and 4.7% at 3 months (Control group) Baseline OS: 36.4 Improved by 2.1% at 4 weeks and 2.7% at 3 months No significant treatment effect (0.6% change).	NA	NA	NA
Roland Morris Score (RMS)	(RF group) Baseline RMS: 52.9 improved by 8.4% at 4 weeks and 9.8% at 3 months (Control group) Baseline RMS: 51.6 improved by 2.2% at 4 weeks and 7.2% at 3 months Difference between groups 6.2% *(p = 0.05)** and 2.6% at 12 weeks (not significant)	NA	NA	NA
Physical Activity	NA	(RF Group) Baseline activity: 19.3 U Physical activity improved by 0.5 U (Control Group) Baseline activity: 19.1 U Physical activity improved in control group by 0.4 U No statistical significance found between groups	(RF Group) Baseline activity: 20.6 U Physical activity improved by 1.5 U (Control Group) Baseline activity: 18.4 U Physical activity improved in control group by 0.9 U No statistical significance found between groups	NA
Patients' own global assessment	NA	NA	Global perceived effect (GPE) scale (4-point Likert scale) (> 50% pain relief) (RF group) 61.5% experienced improvement in back pain 50% experienced improvement in leg pain (Control group) 39% experienced improvement in back pain 36.6% experienced improvement in leg pain GPE also shows RF to be superior to sham in female patients (P = 0.018), older patients (P = 0.022), patients with longer pain history (P = 0.019), patients with employment (P = 0.008), and patients without low back surgery (P = 0.032)	(RF group) Baseline subjective assessment (6-point scale): 3.85 U. Improvement by 1.1 U *(P < 0.001)* (Control group) Baseline subjective assessment (6-point scale): 3.35 U Improvement by 0.3 U *(P = 0.055)* Difference between groups 0.8 U *(p = 0.004)**

* Statistically significant.

the two groups at 12 weeks.

In the case of Geurts et al., VAS-BP and VAS-LP were used as a POC. Measurements were taken at 3 months and performed on a scale of 1–10. Baseline VAS-BP for the treatment group was 5.8U, with pain improving by 0.6U at 3 months. For the control group, baseline VAS-BP was higher at 6.2U but also improved by 1.1U at 3 months. There was no statistical difference in reduction between the two groups ($p = 0.32$). The VAS-LP for the treatment group was 6.1U at baseline with an improvement 0.7U. For the control group the baseline VAS-LP of 6.2U also improved by 2.0U at 3 months.

Van Wijk et al. utilised the VAS-BP and VAS-LP values based on a 0–10 scale. Baseline VAS-BP for the treatment group was 5.8U, with pain improving by 2.1U at 3 months. For the control group, the VAS-BP of 6.5U also improved by 1.6U at 3 months. The baseline VAS-LP of 4.2U improved by 1.1U for the treatment group as did the VAS-LP of 4.1U by 0.7U for the control group.

Nath el al used all three criteria as their primary outcome measures. Their measurements were taken at 6 months. For VAS-GP, the baseline score (on a scale of 1–10) of 6.03U improved by 1.9U for the treatment group. For the control group an improvement of 0.4U was seen on a baseline value of 4.1U at 6 months. The difference in reduction between the groups was statistically significant with a p value of 0.02. The VAS-BP for the treatment group was 5.98U with improvement at 4 months by 2.1U. For the control group, the baseline VAS-BP of 3.88U also improved by 0.7U. The baseline VAS-LP of 4.33U improved by 1.6U for the treatment group, as did the VAS-LP of 2.73U by 0.13U for the control group. Once again, the differences in results were statistically significant for VAS-BP ($p = 0.004$) and VAS-LP ($p = 0.004$).

Analysis of analgesic intake was also performed at baseline and at follow up appointments by all four studies. Leclaire et al. analysed the actual medication (NSAIDs or acetaminophens) taken and showed no significant difference in intake between the two groups at 4 or 3 month follow up. The remains three studies used a more objective analgesia intake scale that was based on either 8-point (Geurts et al. and Van Wijk et al) or 6-point scale (Nath et al). Geurts et al. and Van Wijk et al. showed no statistical significance in consumption between the treatment and control groups. However, Nath et al. showed that the baseline consumption of 4.33U was reduced by 1.4U at 6 months in the treatment group and 3.8U at baseline for the control group by 0.6U for the control group. The difference in intake between the groups was deemed to be statistically significant with $p = 0.04$.

The Oswestry Score (OS) and Roland Morris Score (RMS) was only used by Leclaire et al. The Baseline OS of 38.3 improved by 2.7% at 4 weeks and 4.7% at 3 months for the treatment group whilst the baseline score of 36.4 improved by 2.1% at 4 weeks and 2.7% at 3 months. Statistical analysis revealed no significant treatment effect between groups. Similarly, measurements of functional disability through the RMS showed a baseline of 52.9 improve by 8.4% at 4 weeks and 9.8% at 3 months. For the control group, the baseline score of 51.6 improved by 2.2% at 4 weeks and 7.2% at 3 months. The difference between groups was not statistically significant at both 4 week or at 3 months.

Analysis of physical activity (PA) was done by Geurts et al. and Van Wijk et al. Geurts et al. showed minimal improvement in baseline activity of 19.3U by 0.5U at 3 months for the treatment group. For the control group a similar baseline activity level of 19.1U improved by 0.4U. However, no statistical significance was found between the two groups. Van Wijk et al. showed a baseline PA of 20.6U improves by 1.5U for the treatment groups and 18.4U at baseline by 0.9U for the control group respectively. Once again, no statistical significance was found between the two groups.

A modified 4-point Likert scale was utilised by Van Wijk et al. to assess the Global Perceived Effect (GPE). This was based on the perception of $\geq$50% pain relief. At 3 months, 61.5% of patients had improved back and 50% of patients had improved leg pain. With the control group 39% of patients had improved back and 36.6% of patients had improved leg pain. The GPE also showed RF to be superior to sham in female patients ($P = 0.018$), older patients ($P = 0.022$), patients with longer pain history ($P = 0.019$), patients with employment ($P = 0.008$), and patients without low back surgery ($P = 0.032$). It also showed that the GPE for back and leg pain were in favour of radiofrequency denervation when considering greater than 50% pain relief

Results of the primary and secondary outcome measures have been tabulated below (Table 1).

4. Discussion

Chronic back pain (CBP) develops in about 10–15% of all patients,[31] although many of these patients tend to develop acute exacerbation of their pre-existing symptoms. The lumbar zygapophysial joints have been implicated as one of the potential cause for low back pain syndromes. The use of radiofrequency denervation of the lumbar zygapophysial joints as a modality for pain control has yielded varying results, despite modifications of the original technique first described by Shealy.[13] Given the variability in results from the available literature, this systematic review evaluated the available randomised controlled trials to provide evidence to compare the outcome of radiofrequency denervation compared to sham or placebo procedure in treating chronic low back pain caused by lumber zygapophysial (facet) joints pathology. All studies utilised a double-blinded principle, with improved the methodologic quality of the paper.

4.1. Patients

From a methodologic perspective, three out of four studies had an adequate number of patients that were eligible and subsequently included in the study. Nath et al. screened a slightly small number of patients (376) with 40 patients being eligible. The total number of eligible patients between the studies was 274, of whom 141 received active treatment. All 4 studies had an uneven sex distribution with a higher female to male ratio of eligible patients for both the RF and placebo groups. There was minimal variability in the mean age (46 yrs.) between the RF and placebo groups in the Leclaire et al., Geurts et al. and Van Wijk et al. studies. Nath et al. had a slight older cohort of patient with a mean age of 53 yrs. for the RF group and 53 yrs. for the placebo group. Given the nature of the surgical intervention utilised i.e. invasive technique with additional radiological exposure, the number of patients in each study was deemed appropriate.

4.2. Inclusion criteria

Both Geurts et al. and Van Wijk et al. included patients with lumbosacral back pain lasting more than 6 months' duration. Leclaire et al. included patients with minimum pain duration of 3 months whilst Nath et al. included patients with a minimum of 2 years' duration. The lower number of eligible patients included in the latter study may therefore be explained by the more stringent inclusion criteria of 2 years. All eligible patients were deemed to have a positive response to a diagnostic nerve block performed under fluoroscopic guidance however, due to a high false positive effect; diagnostic blocks should ideally be performed using placebo-controls. None of the four studies utilised a double-blinded placebo-control diagnostic block model to confirm the origin of pain. Geurts et al. and Nath et al. did however administer 3 and 2 separate facet blocks respectively on separate occasions. Patients needed consecutive positive responses from each of the blocks to be included. Conversely, Leclaire et al. and Van Wijk et al. utilised a positive response from a single block.

4.3. Interventions

The RF groups in both Leclaire et al. and Geurts et al. were both treated with a 90 s RF lesion. Leclaire et al. heated the probe to 80 °C, whilst the latter to 67 °C. Leclaire et al. performed two neurotomies for

each nerve i.e. at the proximal and distal portion of the facet nerve. The anatomical location was confirmed by dermatomal anaesthesia produced by injection of local anaesthetic (2mls of 1% lidocaine). The neurotomy was also performed at a minimum of 2 levels, and this was based on the initial facet joint injection. Similarly, Geurts et al. confirmed the location of the dorsal root ganglion by injecting local anaesthetic (3–5mls of 2% mepivacaine) and producing dermatomal anaesthesia. Geurts et al. specifically highlight a modification of the technique used at S1 level by using Kirshner wires. This modification was not utilised by any other study. Van Wijk et al. utilised a 60 s RF lesion, also heated to 80 °C. The electrode positions were confirmed radiologically being at the angle between the superior articular process and transverse process. Dermatomal anaesthesia was also produced by injecting 0.5mls of 2% mepivacaine. Nath et al. utilised a different technique. The position of the electrode was confirmed of 3 radiological views – the tunnel view, postero-lateral view, cephalad view. A lateral view was utilised to ensure that the electrode did not protrude far enough to damage the nerve root. 2mls of 0.5% bupivacaine was injected to anaesthetise the target nerve. A 60 s RF lesion was performed at temperature of 85 °C.The cannula was withdrawn 5 mm and another lesion was made. 4 more lesions were made on either side on the initial 2 lesions. This would account for variations in nerve root anatomy and therefore a higher chance of successfully targeting the nerve root. In total, Nath et al. had 6 RF lesions per nerve root, higher than any of the prior three studies. This technique alone may therefore account for the positive outcome generated solely by this study.

All studies utilised the same technique for their respective control groups, but maintained the electrode sat body temperature.

4.4. Outcome measures

All 4 studies utilised pain relief from a visual analogue score (VAS) as a primary outcome measure. This varied from VAS-generalised pain (Leclaire et al) to VAS-back pain and VAS-leg pain (Geurts et al. and Van Wijk et al) to all three VAS scores (Nath et al). Leclaire et al. utilised a 100-point scale, whilst the remainder a 10-point scale. The time to the primary outcome measure = also varied in that the initial 3 studies used a 3-month VAS assessment (with Leclaire et al. also performing an additional assessment at 4 weeks' time post-intervention). Nath et al. performed their first review at 6 months following the initial intervention. In Leclaire et al. study, pain improved at 4 weeks, for the RF group, but worsened at 3 months. At three months, there was no significant treatment effect between groups.

With Geurts et al. study, both RF and control groups had an improvement in pain for both VAS-BP and VAS-LP, however there was no statistical significance in difference in improvement between groups. In fact, at 3 months the VAS-LP in the control group had improved to a greater extent (reduced by 2.0 U from a baseline of 6.2 U) than the RF group (reduced by 0.7 U from a baseline of 6.1 U) demonstrating statistical significance ($p = 0.02$).

Van Wijk et al. showed that the VAS-BP and VAS-LP improved in both RF and control groups, achieving statistical significance at 3 months. They acknowledge that their results vary from Leclaire et al (where reduction in VAS-GP in both groups from baseline did not achieve statistical significance) and suggest that the administration of a steroid in conjunction with the therapeutic effect of the diagnostic block may have influenced subsequent findings. However, the combined outcome measure and difference in reduction between groups at 3 months showed no differences between RF denervation and sham treatment.

Nath et al showed a positive outcome from their study. At 6 months, VAS-GP had improved in both RF and control groups. However, the extent of improvement was greater following RF denervation (difference in reduction $p = 0.02$). Similar improvements in pain were seen with VAS-BP (difference in reduction $p = 0.004$) and VAS-LP (difference in reduction $p = 0.004$) at 6 months.

All studies also utilised analgesic intake as an outcome measure. Leclaire et al do not specify the methods used to assess analgesia intake or whether a baseline consumption scale was used. Geurts et al and Van Wijk et al utilised an 8-point analgesic scale whilst Nath et al utilised a 6-point scale. Leclaire et al comment no difference in analgesic intake between the RF and control groups at either 4 or 12 weeks based on acetaminophen or nonsteroidal anti-inflammatory intake or non-pharmacological treatment such as physiotherapy. Geurts at et showed minimal improvement in analgesic intake in both groups at 3 months, with no statistical significance found between groups ($p = 0.23$). Van Wijk et al demonstrated a similar outcome with no statistical significance found between groups. Conversely, Nath et al showed a reduction in analgesic intake in both groups, with statistical significance between groups. However, their study does show a higher baseline analgesic intake in both groups with results based on a smaller 6-point scale.

The Oswestry scores and Roland Morris Score were utilised by Leclaire et al. Both had no significant treatment effects at 3 months. An important outcome measure utilised by Nath et al was the 6-point patients' own global assessment scale. At 3 months, patients who underwent RF denervation were deemed to have a statistically significant improvement from baseline ($p < 0.001$). With the control group, the difference from baseline was not statistically significant ($p = 0.055$).

Van Wijk et al utilised a global perceived effect (GPE), which was based on a modified 4-point Likert scale. The GPE for back and leg pain were in favour of radiofrequency denervation, with majority experiencing ≥50% pain relief at 4 months in the RF group. The GPE also showed preference to RF denervation in female patients ($P = 0.018$), older patients ($P = 0.022$), patients with longer pain history ($P = 0.019$), patients with employment ($P = 0.008$), and patients without low back surgery ($P = 0.032$)

4.5. Study conclusion

Based on these outcome measures, only Nath et al state that patients who underwent RF denervation showed statistically significant improvement in outcome measures and therefore should be utilised in carefully selected patients with chronic back pain. Leclaire et al highlight short-term improvement at 4 weeks, but showed no therapeutic benefit at 3 months. They also recommend the use of a more stringent patient inclusion criteria such as patient age. Similarly, Geurts et al do not advocate its use as routine treatment for lumbosacral radicular pain, with no statistical significance between groups at 3 months. Although Van Wijk et al state that the combined outcome measure and VAS showed no difference between RF and sham groups at 3 months, with the GPE being in favour of RF, they recommend RF denervation in selected patients based on the results of the GPE.

Outcomes from the studies included in this systematic review provide conflicting evidence that RF denervation provides therapeutic benefit as a treatment modality for chronic back pain. Additionally, the diagnostic blocks used to identify the source of pain were not placebo-controlled local anaesthetic blocks, which may alter subsequent results. Only one study by Nath et al explicitly advocates its use for LBP. The technique utilised in this study appears to superior, utilising 6 RF lesions compared to the conventional 1 or 2, and this would help target anatomical variations of the nerve root in the body. However, they did have a small number of patients included in their study and their duration of symptoms was significantly longer (2 years) compared to 3 (Leclaire et al) and 6 months (Geurts et al and Van Wijk et al) respectively.

4.6. Applicability to NICE guidelines

The National Institute for Health and Care Excellence (NICE) guideline (NG59) for the assessment and management of low back pain and sciatica in over 16 s recommend referral for assessment for RF

denervation based on 3 criteria:

1. When non-surgical treatment has failed and
2. The source of pain is thought to arise from structures supplied by the medial branch nerve and
3. They have moderate or severe levels of localised back pain (rated as 5 or more on a visual analogue scale, or equivalent) at the time of referral.

They also recommend that RF denervation should only be performed after a positive diagnostic block.

Our systematic review shows that there is still insufficient evidence to support the use of RF denervation as a treatment modality. Whilst the Nath et al study does indeed depict positive outcomes following RF denervation, they had small number of patients included, longer duration of symptoms but what appears to be a superior surgical technique. Therefore, their study design needs to be replicated, in particular, the use of a 6 RF lesions. Immediate, intermediate and long term outcomes based on this methodology should then be assessed. Long-term outcomes extending beyond the 1-year period would help track long-term and delayed adverse effects. Study designs also need to focus on patient demographics, in particular patient age, gender and duration of symptoms.

5. Conclusion

The studies included in this systematic review show conflicting evidence at an intermediate 3–6-month stage. There is evidence form a single study (Leclaire et al) demonstrating short-term benefit at 4 weeks, however, when repeated at 3 months, no difference is shown between RF and sham groups. Nath et al do demonstrate statistical significance between groups at 3 months. Their surgical technique was different, and arguably superior, to the studies in the review. However, their cohort of patient was significantly older, having back pain of at least 2 years' duration. As such, a direct comparison of studies is difficult. There is therefore need of larger, longer, higher-quality randomised control trials with stringent inclusion criteria focusing on patient age, gender, and uniform duration of symptoms. In addition to this, the use of a double-blinded placebo-controlled local anaesthetic block to confirm the origin of pain would be a welcomed addition for methodological improvement. Only with meaningful, standardised outcome measures can the effect of radiofrequency denervation for chronic back pain be delineated.

Conflict of interest

None.

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