Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Health Technology Assessment of Scheduled Procedures

Radiofrequency lesioning for chronic spinal pain

December 2013

Safer Better Care

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1 Radiofrequency lesioning for chronic spinal pain

1.1 Scope of this health technology assessment

This health technology assessment (HTA) evaluates the appropriateness and potential impact of introducing clinical referral and treatment thresholds for radiofrequency (RF) lesioning for chronic spinal pain, a routine scheduled procedure within the publicly-funded healthcare system in Ireland. The effectiveness of RF lesioning for this indication may be limited unless undertaken within strict clinical criteria. This report is one of a series of HTAs of scheduled procedures. Details of the background to the request for the assessments from the Director General of the Health Service Executive (HSE), Mr Tony O'Brien, and the general methodology are included in the separate 'Background and Methods' document.(1)

The scope of this HTA is to recommend clinical referral and treatment thresholds to be used in the assessment, referral and management of patients for whom an RF lesioning procedure for chronic spinal pain is being considered. Input from an Expert Advisory Group as well as a review of international guidelines, international policy documents and thresholds, and economic evaluations were used to inform the referral criteria. Additionally the resource and budget impact were assessed where appropriate. Referral and treatment thresholds for a number of related procedures for chronic pain in adults due to lumbar degenerative spinal disease including spinal surgery, vertebroplasty, spinal injections and spinal cord stimulators are detailed in separate documents accompanying this report.

1.2 Procedure indications

Radiofrequency (RF) lesioning* is increasingly being used to provide long term pain relief in adults with chronic spinal pain.(2) The main indication for RF lesioning is to treat low back pain related to facet joint syndrome associated with lumbar degenerative spinal disease. However it is also used for cervical, lumbar and sacroiliac joint-related pain. The facet joints are paired structures at the back of each vertebra that form a working motion unit that allows movement between two vertebrae – medial branch ablation targets the nerves carrying pain from these facet joints. It is reported that facet joint pathology is a contributory factor in 15% to 45%

* There is some variation in procedure terminology in the literature, for the purpose of consistency this report will use radiofrequency (RF) lesioning, which encompasses classical RF ablation (uses a heat lesion) and pulsed RF (uses short bursts of electrical current of a high voltage without heating the tissue). Section 2.1 to 2.3 reviews the literature for RF lesioning; the original terminology used in the literature is included in these sections to avoid any misinterpretation of results.

of patients with low back pain, 36% to 67% of patients with neck pain, and 34% to 48% of those with localised thoracic pain.[3-6] RF lesioning (using pulsed RF) is also used to treat peripheral nerve pain, however this indication is beyond the scope of this HTA.

Most episodes of low back pain are short lived, with 80% to 90% of attacks resolving within six weeks, irrespective of the type of treatment administered. Low back pain can be broadly classified as being due to a specific cause (for example, spinal instability, spondylosis, spinal stenosis, discogenic back pain, disc herniation or prolapse) or as non-specific back pain that cannot reliably be attributed to a specific disease or spinal abnormality.[7;8] Most patients with acute low back pain improve substantially over the first month. After the first month, improvements are less pronounced and eventually taper off. In a small minority of patients, back pain is persistent and disabling.[9] The International Association for the Study of Pain (IASP) defines chronic pain as persisting beyond normal tissue healing time, assumed to be three months, while the UK National Institute of Health and Care Excellence (NICE) defines chronic low back pain as pain, muscle tension or stiffness in the lower back region, with or without leg pain that persists for longer than six to twelve weeks.[7] Treatment strategies include structured conservative management in addition to surgical and other interventions. Guidelines for the management of acute and chronic back pain (including non-specific back pain) are available from organisations such as NICE, the American Society of Interventional Pain Physicians and the American Society of Anaesthesiologists.[2;7;10]

Prevalence rates predict that low back pain is a common problem affecting around one-third of the adult population each year,[7;9] particularly working-age adults, with peak incidence occurring in people aged between 25 and 64 years.[11] Annual prevalence of chronic low back pain ranges from 15% to 45%,[4;12] and 26% to 71% for chronic neck pain,[5] with a lifetime prevalence of spinal pain reported as 49% to 90%.[4;11-13] Thoracic pain symptoms (due to radicular pain [which is multi-factorial] or facet pain) are less common, comprising an estimated 5% of patients referred to outpatient pain clinics.[6;8;11]

1.3 Procedures, potential complications and alternative treatments

Radiofrequency (RF) lesioning interventions for pain management comprise classical RF ablation (using heat) and pulsed RF treatment. Classical RF ablation is also termed RF ablation, RF neurotomy, RF denervation or RF rhizotomy. Both RF lesioning techniques involve percutaneous introduction of a catheter with an

electrode. Fluoroscopy imaging is used to guide placement of the electrode through an insulated, cannulated needle to the target nerve. The nerve is then stimulated to ensure correct localisation. Following administration of a local anaesthetic, classical RF ablation uses a constant output of high-frequency electric current for up to 90 seconds, achieving a tissue temperature of up to 80ºC and producing controllable tissue destruction (thermal lesion) surrounding the tip of the cannula. This aims to destroy the sensory nerve fibres and interrupt the pain signals.[2;6;14] In contrast, pulsed RF uses short bursts of electrical current of a high voltage without heating the tissue enough to cause coagulation (less than 42ºC). It is usually applied for a total of four minutes using repeated cycles of pulsed RF for 20 milliseconds with a wash-out period of 480 milliseconds. The mechanism of action of pulsed RF therapy is uncertain: it is a newer procedure, with a shorter duration of action than classic RF ablation. Pulsed RF is not associated with post-procedural deafferentation pain, which is common with classic RF ablation, and because it does not cause tissue destruction, is associated with a lower risk of serious complications. It is indicated in the management of a number of conditions where classical RF lesioning is contra-indicated (e.g. peripheral mono-neuropathies).[2;14-16]

During classical RF ablation of the medial branch of the facet joint, three or four levels are targeted during an intervention session with three to five lesions of each medial branch ablated per level, taking approximately 45 to 60 minutes. Patients are typically booked in for three to four hours, although this may extend to five hours if sedation is required. Prior to the procedure, patients typically undergo a series of diagnostic facet injections to verify the exact source of their symptoms. If the pain can be eliminated or significantly relieved with a local anaesthetic block for a short term, then blocking the nerves with classical RF ablation will usually give long-term relief. These diagnostic injections are undertaken as a separate procedure with the patient rebooked for classical RF ablation on a later date if at least 50% reduction in pain was achieved. Inpatient admission following either procedure is rarely required.[17] Patients may experience an increase in pain for five to seven days after classical RF ablation with maximal pain relief achieved within two to three weeks. The relief of pain typically lasts for six to twelve months.[2;5;18] Pain recurs when the nerves regenerate, but the procedure can be repeated in patients who obtained an adequate response to the first procedure.[19] Expert opinion recommends a maximum of two to three classical RF ablation sessions a year and a lifetime limit on the number of procedures being imposed due to concerns about radiation exposure.[17;20]

The most common complication of classical RF ablation is post-procedural pain. This is usually temporary due to neuritis; burning or dysaesthesias, allodynia or decreased sensation may also occur.[6;11] Most problems, such as local swelling and pain at the

site of the needle insertion are short lived and self limiting. More serious complications may rarely include: dural puncture, spinal cord trauma, subdural injection, neural trauma, injection into the intervertebral foramen, and haematoma formation; infectious complications including epidural abscess and bacterial meningitis; and side effects related to the administration of local anaesthetics.[2] A 2004 study (n=616 lesions, 92 patients) assessing the incidence of complications associated with fluoroscopically-guided percutaneous classical RF ablation of the lumbar facet joints reported an overall 1% incidence of minor complications per lesion site.[21] Pulsed RF treatment appears to be well tolerated and associated with few, if any adverse events.[14-16] Classical RF ablation for cervical or thoracic pain (above the level of Th7) is technically complex, requiring extensive skills. Evidence-based guidelines therefore recommend that these procedures be limited to specialist centres.[6] Although published literature suggests that serious complications are extremely rare, potential complications of classical RF ablation include serious neurological sequelae with spinal cord damage leading to quadriplegia and spinal cord infarction.[5]

Evidence-based practice guidelines recommend that therapeutic and diagnostic interventions used in the management of chronic spinal pain are provided using meticulous aseptic technique in a sterile operating room or a procedure room with clean air that contains the appropriate monitoring, radiological and specialist equipment for the planned intervention. There should be access to facilities for immediate resuscitation, particularly for interventions in the cervical or thoracic spine region.[4;22]

1.4 Current practice in Ireland

RF lesioning procedures are routine scheduled procedures in the publicly-funded healthcare system in Ireland. The Hospital In-patient Enquiry (HIPE) Scheme reports that there were approximately 1,500 procedures undertaken in 2011. The current HIPE data do not provide sufficient detail to allow disaggregation by procedure type (no specific code for pulsed RF) or treatment location (segmental nerve or peripheral nerves).[20] Therefore, the data reported encompass both classical RF ablation and pulsed RF procedures for segmental and peripheral nerves. RF lesioning may be coded as the principal procedure or as a secondary procedure. For consistency and completeness, data are reported to include the principal and secondary procedures (i.e. 'all procedures') with all data presented on this basis. The International Classification of Diseases (ICD) intervention codes used to retrieve this data are listed in Table 1.1. In 2011, approximately 74% of the 1,500 procedures were coded using the intervention code 39118-00, with the remainder using 39323-00.

Table 1.1 HIPE ICD-10AM/ACHI list of codes for RF lesioning

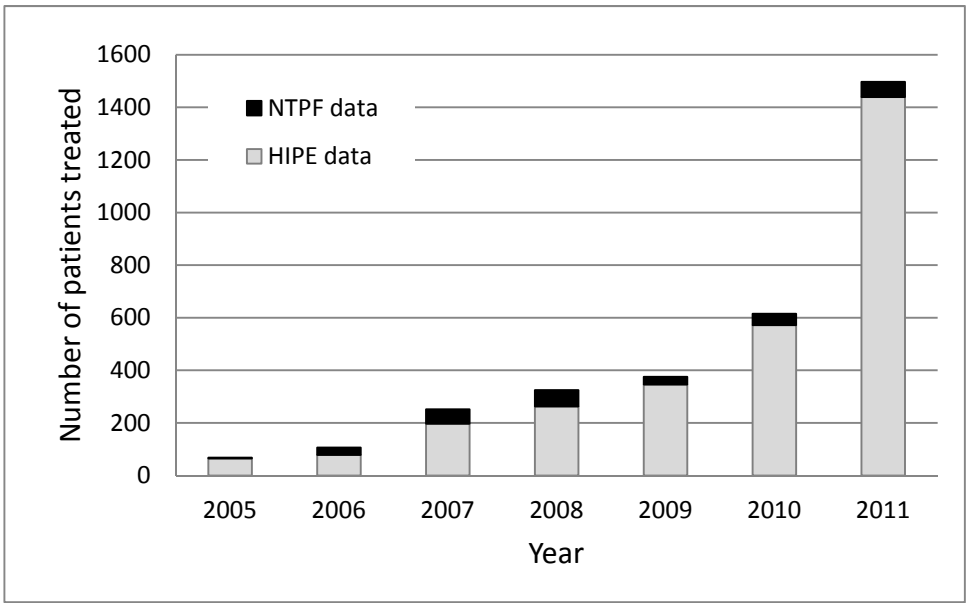
Intervention Code*	Description
39118-00	Percutaneous neurotomy for facet joint denervation by radiofrequency *Includes:* radiofrequency: ▪ ablation ▪ probe
39323-00	Other percutaneous neurotomy by radiofrequency *Includes:* radiofrequency: ▪ ablation ▪ lesion generator ▪ thermocoagulation

**Note: These codes may overestimate the numbers of classical RF ablation procedures as the codes are not specific to this technique. Note: 90027-00 (Intradiscal electrothermal therapy [IDET]) is not included, the procedure is not recommended based on international literature[2;7] – there were no IDET procedures recorded in Ireland in 2011.*

Current data do not permit identification of the precise indication for which procedures are performed as the intervention and diagnosis codes are not linked. HIPE data capture the principal and up to 29 secondary diagnoses recorded in the patient medical notes for each episode of care. In the 2011 HIPE data, lumbosacral pathology was coded as the principal diagnosis in 50% of cases coded as an RF lesioning procedure, while 12% and 4% of cases were coded as having cervical or thoracic pathology as their principal diagnosis.[23] Audit data provided by one hospital indicate that approximately 47% of RF lesioning provided by them is pulsed RF treatment of peripheral nerves, with an estimated 15% of procedures relating to pain management in cancer patients with metastatic disease. These indications are beyond the scope of this HTA. They note that chronic facet joint pain of lumbar and sacroiliac origin (50% and 12% of all procedures, respectively) is primarily treated using classical RF ablation, while chronic facet joint pain of cervical or thoracic origin (9% and 4% of all procedures, respectively) is primarily treated using pulsed RF. Pulsed RF of the dorsal root ganglion accounts for 21% of procedures; this intervention may be combined with either a selective nerve root injection of the relevant segmental nerve or a transforaminal epidural.[24]

The number of RF lesioning procedures undertaken in the publicly-funded healthcare system has increased more than twenty-fold since 2005 (Figure 1.1). In addition to activity levels in public hospitals, a small number of RF lesioning procedures have also been procured for the public healthcare system in private hospitals via the National Treatment Purchase Fund (NTPF).[25] Data on the total number of procedures undertaken in the publicly-funded system and including the additional procedures funded by the NTPF are shown in Figure 1.1.

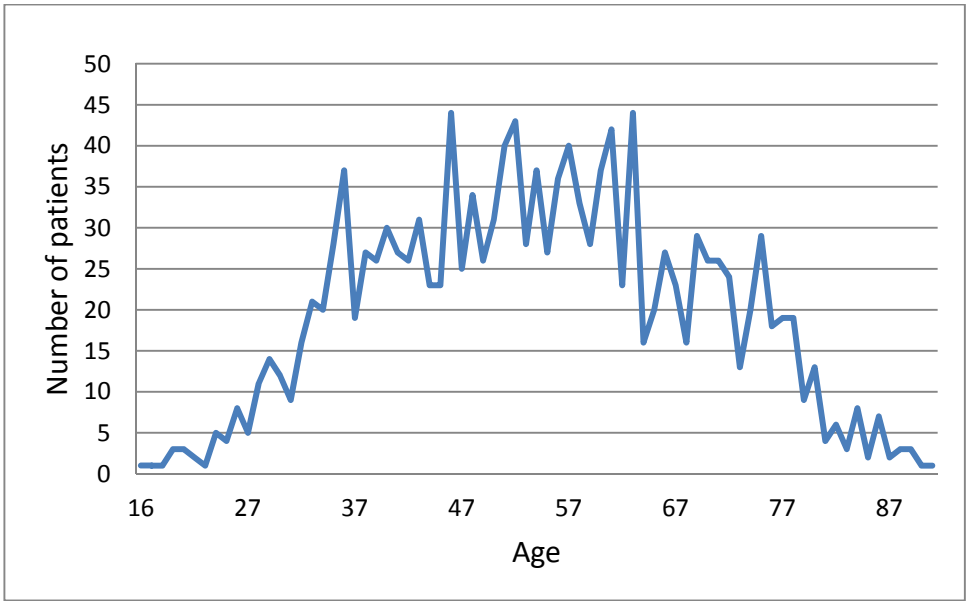
Figure 1.1 Number of RF lesioning procedures provided through the publicly-funded healthcare system (2009 – 2011)



HIPE: Hospital In-Patient Inquiry (HIPE) Scheme, NTPF: National Treatment Purchase Fund. HIPE data include all activity in publicly-funded hospitals, including procedures in patients that used private health insurance. RF lesioning procedures include classical RF ablation and pulsed RF. Source: HIPE data accessed via ESRI HIPE Online Portal April 2013.

The majority (80%) of RF lesioning procedures in Ireland are undertaken in adults aged between 30 and 70 years (Figure 1.2).[23]

Figure 1.2 Age profile of patients undergoing RF lesioning (2011)



HIPE: Hospital In-Patient Inquiry (HIPE) Scheme; RF lesioning includes classical RF ablation and pulsed RF. HIPE data include all activity in publicly-funded hospitals, including procedures in patients that used private health insurance.

Source: HIPE data accessed via ESRI HIPE Online Portal 28 January 2013, NTPF activity data.

HIPE data indicate that RF lesioning procedures are undertaken predominantly by pain specialists (96%).[23] The availability of this procedure is therefore restricted to facilities with this service. The data indicate that RF lesioning was provided in 11 different hospital locations in 2011; seven hospitals recorded fewer than 10 procedures each. Table 1.2 provides a breakdown of activity by the proposed Health Service Executive (HSE) hospital groups that were recently announced by the Department of Health.[26] This shows large variation across the hospital groups with 78% of all procedures provided by the South/South West group. This variation may be explained by differences in the size and specialisation of catchment areas or the availability of a pain relief specialist service with people trained in this procedure, resulting in the development of regional or supraregional specialist centres. Expert feedback suggests that inaccurate data coding may be contributing to under-reporting of this procedure in some hospitals as the HIPE data do not correlate with local estimated activity rates.[27]

Table 1.2 HIPE data per proposed HSE hospital group* (2011)

Hospital group	Number (%)	ALOS (days)	Inpatient bed days	% day case	Avg. age (years)
Dublin North East	5 (0.4)	35	70	60	63.0
Dublin Midlands	212 (14.7)	0	0	100	57.7
Dublin East**	N/R	N/R	N/R	N/R	N/R
South/South West	1,118 (77.7)	3.2	443	93.6	50.9
West/North West	6 (0.4)	1.2	7	0	54.5
Midwest	96 (6.7)	18.5	37	97.9	53.4
Acute paediatric services, Dublin	-	-	-	-	-

** Data by proposed HSE hospital groups.[26] HIPE data include all activity in publicly-funded hospitals, including procedures in patients that used private health insurance.*
*** Data not reported (N/R) as consists of five or fewer cases.*

HIPE data indicate that 94% of RF lesioning in 2011 was undertaken as day case procedures – this rate has been consistently high since 2005. For the 6% of cases coded as inpatient procedures average length of stay ranged from zero to thirty-five days; however, this data should be interpreted with caution given that the data incorporate procedures undertaken both as secondary and primary procedures (i.e. patient admitted for another reason and subsequently referred for specialist pain review) and the likelihood that the inpatient data is highly skewed by a small number of admissions.

Most patients with chronic back pain should be offered structured conservative management, which includes physiotherapy, prior to referral for specialist review.

Access to physiotherapy in the primary care setting is reported to be limited, with the result that it appears that some patients are currently being referred without meeting this criterion. Since March 2012, a triage scheme involving 24 specialist musculoskeletal (MSK) advanced practice physiotherapists has been in operation nationally (although not all hospitals) as a waiting list reduction initiative by the HSE's Orthopaedic and Rheumatology Clinical Programmes. Under this scheme, patients who have been referred to secondary care are initially triaged by the specialist, who can decide which patients are suitable for referral to an MSK physiotherapist for treatment; those whose symptoms persist following treatment are referred back to the specialist, while those whose symptoms subside may be referred back to primary care. Although yet to formally report, anecdotally it is noted that only approximately 15% of patients are referred back to the surgeon to be considered for a spinal procedure.[17] Separately, in a retrospective study of primary care referrals to one triage programme that provided initial assessment and management by an MSK physiotherapist it has been reported that 85% of patients were suitable for conservative management (group or individual therapy), 14% were discharged and only 1% required onward referral for specialist opinion.[28] Back pain triage clinics have also been established by some hospitals to facilitate timely access to appropriate services. These use stated referral criteria, standardised referral forms and triage processes for accessing orthopaedic, pain specialist, rheumatology and specialist physiotherapy services. It is recommended that unless urgent, patients access physiotherapy within the primary care system prior to referral to the triage clinic.[29] While the use of such stated criteria provide clarity, facilitate timely access and streamline the efficient use of resources, they do not eliminate wait times if need exceeds available capacity.

Referrals to pain specialists may be from the primary care setting or from other hospital-based specialists including orthopaedic, rheumatology and neurosurgical services. The length of time a patient must wait to be reviewed varies according to the referral pathway and the individual hospital and consultant to which a patient is referred. At the end of August 2013, it was reported that there were 374,104 patients on the Outpatient Waiting List database collated by the NTPF, 58% of whom were waiting less than six months, with 78% waiting less than 12 months. Ten hospitals reported 3,820 patients on outpatient waiting lists to see pain relief specialists, with 50% and 74% of patients reported as waiting less than six and 12 months, respectively, at that time.[30] Initiatives are underway by the HSE to standardise the management of outpatient services and to ensure that there are consistent management processes across all publicly-funded healthcare facilities that provide outpatient services. This includes the publication of a protocol for the management of these services by the NTPF in January 2013 which provides the core

guidance of the Outpatient Services Performance Improvement Programme.[31] The protocol specifies that patients should be treated based on clinical urgency, with urgent referrals seen and treated first. It is intended that the definition of clinical urgency and associated maximum wait times is to be developed at specialty or condition level and agreed by the National Clinical Programmes.

In January 2013, the NTPF published a national waiting list management policy that outlines the standardised approach to managing scheduled care treatment for inpatient, day case and planned procedures in all publicly-funded hospitals. It outlines a consistent structured approach that must be adopted to the management of the waiting list; monitoring of the implementation of the policy will be routinely undertaken by the NTPF in the form of annual quality assurance reviews.[32] Data from the NTPF reflecting surgical and medical inpatient and day case waiting lists for all public hospitals (44 hospitals) indicate that there were 73 patients (ICD codes: 39118-00, 39323-00) on the waiting list for RF lesioning in April 2013. Thirty-two percent were waiting less than three months, 36% were waiting three to six months and 33% for six to twelve months.[33]

It is unclear what proportion of those referred for outpatient review with chronic spinal pain are subsequently listed for RF lesioning. Use of clear referral criteria and treatment thresholds may help clarify the criteria under which referral for this procedure should take place and potentially limit the number of inappropriate referrals.

2 Clinical referral/treatment threshold

2.1 Review of the literature[†]

A comprehensive review of the literature was conducted during June 2013 to identify international clinical guidelines, health policy documents describing treatment thresholds that are in place in other health systems, and economic evaluations for RF lesioning. A detailed summary of these documents may be found in Appendix 1 and 2. The approach and general search terms are described in Appendix 1 in the 'Background and Methods' document; a summary of the results is included in Table 2.1.

[†] The literature reports some confusion in the terminology used for RF lesioning. As such, the original terminology used in the literature is included in this section of the report to avoid any misinterpretation of results.

Table 2.1 Included evidence sources to inform clinical referral thresholds

Publication Type	Number	References
Clinical guidelines	8	(2;4;7;9-11;34;35)
Systematic reviews	6	(6;36-40)
Clinical studies	5	(41-45)
Cost-effectiveness studies	3	(42;46;47)

2.2 Clinical evidence

Evidence-based clinical guidelines have been developed by a number of organisations for the evaluation and management of chronic spinal pain that include recommendations regarding the use of conventional RF ablation and pulsed RF therapy for cervical, thoracic and lumbar facet joint pain, cervical and thoracic radicular pain, and for sacroiliac joint interventions. These guidelines, which differ in their recommendations, are supported by findings from a number of systematic literature reviews and meta-analyses, details of which are provided below.

Updated evidence-based guidelines from the American Society of Interventional Pain Physicians (ASIPP) published in 2013 concluded that the evidence for conventional RF ablation in managing chronic low back pain of facet joint origin in the lumbar spine is good for short- and long-term relief based on seven RCTs of RF ablation, of which six had positive findings.[2] This guideline is supported by a meta-analysis of six RCTs reported in a 2012 review by van Zundert, which showed RF ablation to provide significantly better outcomes than placebo; however, it noted that good patient selection as demonstrated by a successful response to lumbar facet joint nerve block is imperative for good clinical outcomes.[40] It is also consistent with 2010 published guidelines for chronic pain management from the American Society of Anaesthesiologists (ASA), which advised that there is Category A1 evidence to support the use of classical RF lesioning for facet joint pain based on a meta-analysis showing lower post-procedure pain scores for assessment periods of two to six months in patients with low back pain.[9] An updated systematic review published in 2012 on the effectiveness of therapeutic lumbar facet joint interventions also concluded that there is good evidence for the use of classical RF ablation for the treatment of chronic lumbar facet joint pain resulting in short-term and long-term pain relief and functional improvement. Evidence for pulsed RF treatment for chronic lumbar facet joint pain, however, was noted to be limited.[48] Furthermore, based on two comparative randomised trials, it is suggested that pulsed RF is less effective (shorter duration of response) than classical RF ablation in the management of lumbar facet joint pain.[15]

A 2009 clinical guideline from NICE recommended that patients with persistent or recurrent low back pain (defined as non-specific low back pain that has lasted for more than six weeks, but for less than 12 months) should not be referred for RF facet joint denervation for non-specific low back pain.[7] This was based on results from three small RCTs.[43-45] Similar evidence-based clinical practice guidelines developed by the American Pain Society (APS) in 2009 for the management of low back pain in adults[9;35] suggested that that there was insufficient evidence to adequately evaluate benefits of radiofrequency denervation for non-radicular low back pain. These guidelines noted the limitations in the evidence base,[6;43-45] which included inconsistent results between trials as well as technical and methodological shortcomings[38] that make it difficult to reach conclusions about benefits. The findings of these trials have been disputed, with criticism that the negative results reports were due to poor patient selection and surgically inaccurate techniques.[36;49] Subsequent guidelines developed by the British Pain Society (2013) have suggested that classical RF ablation should be considered as part of multi-disciplinary care in patients with chronic low back pain that has been confirmed to be of facet joint origin using median branch blocks, but that clear thresholds and exclusions should apply.[50] A similar recommendation is also made in a 2013 NHS Commissioning guide for low back pain developed by three professional surgical associations, which recommends that RF ablation of lumbar facet joints should only be undertaken after a successful lumbar facet joint nerve block and as part of a multi-disciplinary managed programme of care which includes the chronic pain service.[51] Likewise, 2011 published guidelines from Toward Optimised Practice in Canada on evidence-informed primary care management of low back pain recommend that 'medial branch neurotomy' may be beneficial for carefully selected patients with a clinical diagnosis of pain originating from the lumbar facet joints.[11]

Interventional practice guidelines published in 2009 suggest that classic RF ablation is recommended (level 2C+) for the management of thoracic facet joint pain on the basis of two small prospective studies that noted up to 82% of patients achieving a 50 to 75% reduction in pain symptoms two months after treatment.[6] This recommendation suggests that this intervention should preferably be provided only as part of a clinical study due to the limited evidence base. Similarly the 2013 American Society of Interventional Pain Physicians (ASIPP) guidelines noted the evidence for therapeutic thoracic facet joint pain to be limited, but emerging based on two small prospective trials that indicated at least a 50% reduction in pain in 68% of patients that was sustained for up to nine months.[2]

Interventional practice guidelines for the management of thoracic radicular pain published in 2009 recommended that pulsed RF treatment of the thoracic dorsal root

ganglion could be considered in the management of therapy-resistant thoracic radicular pain, preferably as part of a clinical study (level 2C+). This limited recommendation was on the basis of two small observational studies that indicated 52 to 70% of patients experienced significant pain reduction for periods ranging from nine to forty-six months. The guidelines noted that classical RF ablation could be considered if the response to pulsed RF is short lasting and the pain is segmental, (level 2C+), but that this procedure is technically complex above the level of Th7, and its use should be limited to specialist centres, and preferably be study related.[6]

Updated evidence-based guidelines from the ASIPP published in 2013 concluded that the evidence for conventional RF ablation in the management of cervical facet joint pain is fair based on one sham-controlled RCT, four prospective studies and one retrospective evaluation.[2] A 2012 systematic review of cervical facet joint interventions concurred that the evidence to support classical RF ablation was fair based on multiple moderate quality observational studies and one high quality RCT by Lord et al.[52] that indicated 58% of patients in the active treatment group achieved significant pain relief that was sustained to at least 50% of the pre-operative level for approximately nine months.[5]

Interventional practice guidelines{Van Zundert J., 2010 1240 /id} for the management of cervical radicular pain published in 2010 provided a positive recommendation for pulsed RF treatment adjacent to the cervical dorsal root ganglion for chronic cervical radicular pain (level 1B+). This evidence was based on one placebo-controlled RCT and one RCT comparing pulsed RF to classical RF ablation that indicated a similar significant reduction in pain at six weeks and three months post-intervention for both groups. Due to the higher risk of serious adverse events, the use of classical RF ablation was recommended only for those who have an insufficient response to pulsed RF treatment or if the benefit was limited to a short duration. It recommended that classical RF ablation for this indication should preferably be study-related (2B+). A recent systematic review published in 2011 concurred with this finding.{Falco, 2012 1237 /id}

For sacroiliac joint interventions, 2013 guidelines from the ASIPP concluded that the evidence for both conventional and pulsed RF lesioning is limited. Evidence for classical RF ablation was limited to one retrospective evaluation (n=77 patients) in which 53% of patients reported a reduction in pain levels at six months. Similarly, evidence for pulsed RF lesioning was limited based on one small observational study (n=22) over six months that reported at least 50% reduction in pain levels for periods ranging from six to thirty-two weeks in 73% of patients who had previously failed conservative management.[2] Other systematic reviews have concurred with this finding, suggesting that the evidence for RF lesioning in the management of

sacroiliac joint pain is still emerging, which limits the conclusions that can be drawn. However, the limited data suggest that significant improvement in pain scores and functional status can be obtained in carefully selected patients. The need for randomised studies with well defined selection criteria, larger sample sizes and relevant long-term outcome measures is recommended to determine their role.[53]

The remaining systematic reviews and health technology assessment findings are summarised in Appendix 1. In the UK, service delivery for the National Health Service (NHS) was until recently the responsibility of local primary care trusts (PCTs). Many of these PCTs generated treatment thresholds for elective procedures (including RF lesioning) that were linked to the funding of these interventions, identifying interventions that were 'not normally funded' or that must meet specified criteria for funding to apply. The PCTs were officially disbanded in March 2013 and their responsibilities taken over by Clinical Commissioning Groups (CCG) and the NHS Trust Development Authority. However, PCT thresholds are likely to represent ongoing practice at a local level while new commissioning guides are being developed. Examples of three PCT policies are included in Appendix 1 along with examples of evidence-based treatment thresholds used by US health insurers. Many US reimbursement agencies consider pulsed RF experimental and investigational for several indications including low back pain and will not reimburse for this procedure.[54;55]

In summary, there is limited and sometimes conflicting evidence relating to the use of classical RF ablation and pulsed RF therapy in the management of chronic cervical, thoracic, lumbar and sacroiliac spinal pain, with some evidence developing over time for carefully selected patients. Although the specific suggestions about timing of referral are not clear from the literature, criteria developed by the US reimbursement agencies and UK primary care trusts include conservative management of at least six months' duration[56] or that the patient should have 'experienced severe pain limiting activities of daily living for at least six months' and 'failed conservative treatment'.[55;57]

2.3 Cost-effectiveness evidence

A 2010 multi-centre, randomised, comparative cost-effectiveness study comparing 0, 1, and 2 diagnostic medial branch (facet joint nerve) block treatment paradigms before lumbar facet radiofrequency denervation reported that the costs per successful treatment in groups 0, 1, and 2 were US$6,286, US$17,142, and US$15,241, respectively.[42] Using reimbursement scales current at the time, it suggested that proceeding to radiofrequency denervation without a diagnostic block is the most cost-effective treatment paradigm.

2.4 Budget impact and resource implications

The estimated average cost of an RF lesioning in Ireland in 2011 is included in Table 2.2. The HSE National Casemix Programme does not include a diagnosis-related group (DRG) specifically for RF lesioning; therefore, more general DRG codes are included to give an estimate of the cost. HIPE discharge data suggests that 70% (I68C), 9% (I71B) and 6% (B71B) of procedures in 2011 used these codes.[23] Using these DRG codes, this equates to an approximate annual total cost of €800,000 in 2011 for 1,200 procedures (85% of all procedures), or a weighted average cost of €667 per procedure. Procedure cost may vary depending on whether re-usable or disposable ablation catheters (high unit cost) are used. This cost is consistent with findings of an e-survey of European pain medicine practice that was undertaken in 2012 to explore the variation in the functional constitution of pain clinics in Europe. Eighty-two pain practitioners (13 countries, mainly the UK) responded. Two-thirds of respondents reported the cost of four-joint 'RF lumbar denervation' to be less than €1,500.[47] Although the initial costs for RF lesioning can be high, these are offset by a reduction in pain medication costs.

Table 2.2 Cost of HSE inpatient and day case surgery summarised by diagnosis-related group (based on 2011 costs and activity)

DRG code	Description	Cost/case (€)
I68C	Non-surgical spinal disorders, same day	202
I71B	Other musculotendinous disorders without catastrophic or severe complication or comorbidity	2,056
B71B	Cranial and peripheral nerve disorders without catastrophic complication	3,784
-	Outpatient appointment	130

Data summary from the HSE National Casemix Programme based on activity and costs reported by 39 participating hospitals.
Note: there are no specific codes for RF lesioning, the nearest codes are included and as such provide an estimate of the cost.

HIPE data indicate a twenty-fold increase in the number of RF lesioning procedures since 2005. This is consistent with international trends reporting substantial increases in the use of minimally invasive spinal interventions, including RF ablation and pulsed therapy for chronic spinal pain.[58]

2.5 Advice on treatment threshold

There is some controversy in the literature regarding the efficacy of RF lesioning for the management of chronic spinal pain. With this in mind, and in consideration of the relevant guidelines and thresholds recommended internationally, and the evolving evidence base, the following criteria are advised:

Classical RF ablation i.e. radiofrequency facet joint lesioning of the medial branch of the dorsal rami is recommended for the management of non-radicular cervical or lumbar facet joint pain only if the following criteria are met:

- patients aged over 18 years
- failure of six months of conservative treatment, such as medication and physiotherapy
- one anaesthetic diagnostic block of the medial branch of the dorsal rami innervating the target facet joint has been administered and a significant reduction in pain has been demonstrated and recorded following the block during activities that normally generate pain. The pain relief must be consistent with the expected duration of the anaesthetic block
- treatment is provided as part of a comprehensive pain management programme.
- a maximum of four facet joint denervations are provided per treatment episode
- at least six months have elapsed since prior treatment for patients undergoing a repeat procedure at the same site.

Currently there is limited evidence to support the use of classical RF ablation for thoracic or sacroiliac facet joint pain. Use of these procedures is recommended if the above criteria are met and the intervention is provided in the context of special arrangements for clinical governance and clinical audit.

Classical RF ablation is not recommended for early management of persistent non-specific low back pain.

Evidence is emerging, but is currently limited, to support the use of pulsed RF lesioning for cervical or thoracic radicular pain. Use of these procedures is recommended if the following criteria are met:

- patients aged over 18 years
- failure of six months of conservative treatment, such as medication and physiotherapy
- is provided as part of a comprehensive pain management programme.

- the intervention is provided in the context of special arrangements for clinical audit.

All procedures should be performed aseptically under fluoroscopy (x-ray guidance) in a facility with clean air equipped with the appropriate monitoring and specialist equipment for the planned intervention, including facilities for immediate resuscitation.

3 Discussion

Radiofrequency lesioning is a routine procedure in the Irish healthcare system (n=1,439 in 2011) with variation in practice due to localised specialisation. There has been a greater than twenty-fold increase in procedure numbers since 2005, which is consistent with trends in international practice. Of note, HIPE data include all activity in publicly-funded hospitals, including procedures in patients that used private health insurance. Concern has been expressed in relation to the accuracy of the HIPE data as expert feedback suggests that inaccurate data coding may be contributing to under-reporting of this procedure in some hospitals as the data retrieved do not correlate with local estimated activity rates. Initiatives by the clinical care programmes and the Faculty of Pain Medicine to develop pragmatic solutions to ensure that practitioners are consistently using the same codes for the same procedures would help improve data accuracy, so that it reflects actual activity levels.

One limitation of RF lesioning is that the nerves regenerate over time with pain relief being temporary in most patients, necessitating repeat procedures. However, carefully selected patients who respond to initial treatment may experience pain relief for an average of eight to fourteen months, extending to years in some patients. The literature suggests that classical RF ablation should not be used for early management of persistent non-specific low back pain, but that there is evidence for its use in the management of chronic low back and neck pain of facet joint origin to provide short- and long-term relief. The evidence is currently limited for RF ablation of thoracic or sacroiliac joint pain. Evidence to support the use of pulsed RF, which is a newer procedure, is currently limited. Given its favourable adverse event profile, it potentially represents an attractive alternative to classical RF ablation for chronic cervical and thoracic facet joint pain, particularly given the risk of serious neurological sequelae with classical RF ablation at these sites. However, the need for further good quality clinical research to clarify the role of these procedures is urgently needed, with the suggestion therefore that these procedures should only be provided in the context of special arrangements for clinical governance and clinical audit.

The number of RF lesioning procedures performed in the publicly-funded system is not expected to reduce as a result of implementing stated treatment thresholds. As noted, and consistent with international trends, there has been a substantial increase in the number of RF lesioning procedures undertaken in Ireland. There is evidence of substantial variation in regional activity, which may indicate differences in access or clinical practice, with potential differences in how patients are prioritised at a local level. Implementing standardised national referral and treatment criteria should reduce regional variation and improve access for those with the greatest clinical need.

A caveat to the effective implementation of referral thresholds in Ireland is the limited access to conservative management (physiotherapy) in the primary care setting. Of note, initiatives are underway by the Orthopaedic and Rheumatology clinical care programmes in the HSE to develop interface clinics and consultations between primary and secondary care services in Ireland and to implement agreed national referral guidelines for all patients with musculoskeletal disease. This should help to ensure that patients who do not meet the criteria for surgery or other intervention have timely access to appropriate high quality care in the primary care setting.

The suggested referral criteria reflect existing best practice in Ireland. Consistent application of the criteria throughout the healthcare system through the use of stated thresholds that are integrated into agreed national referral guidelines should assist patient triage, bring greater transparency, ensure equity of access based on clinical need and allow maximal benefit to be gained from existing resources. Consistent with best practice, guidelines and thresholds should be updated as necessary to reflect changes in the evidence base. Finally, as outlined in the ethical analysis report, if clinical referral or treatment thresholds are implemented, it is imperative that there are opportunities for appeal mechanisms to ensure good governance.

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Appendix 1 – Examples of international clinical referral thresholds

Guideline	Scope	RF ablation thresholds	Evidence
American Society of Interventional Pain Physicians (ASIPP)(2013)[2] **US**	**Indications:** Chronic spinal pain **Population:** Not specified	*An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: Guidance and recommendations:* The evidence for therapeutic lumbar facet joint interventions is good for conventional RF, limited for pulsed RF. For sacroiliac joint interventions, the evidence is limited for both pulsed RF and conventional RF neurotomy. The evidence for therapeutic cervical facet joint interventions is fair for conventional cervical RF neurotomy. The evidence is limited for therapeutic thoracic facet joint RF neurotomy. (Note: This is an update to the guideline produced in 2009 by Manchikanti et al.[12])	**Literature review:** Systematic review **Grading system:** Developed own system based on various publications **Key references:** Falco 2012, Datta 2009
NICE CG88 (2009)[7] **UK**	**Indications:** Low back pain **Population:** Not specified	*Low back pain. Early management of persistent non-specific low back pain:* Scope: Early treatment and management of persistent or recurrent low back pain, defined as non-specific low back pain that has lasted for more than six weeks, but for less than 12 months. It does not address the management of severe disabling low back pain that has lasted over 12 months. Reported on three RCTs. One 'well conducted' RCT (2001) concluded that RF facet joint denervation is not shown to be of benefit as determined by functional disability at 12 weeks and no effect on pain at four or twelve weeks. A second RCT (2008) with 'high risk of bias' was also reported on, author concluded that RF neurotomy can be successfully used as a complement to other interventions to reduce pain in carefully selected patients. NICE reports that the sample size was small and results could be confounded. The third 'well conducted' RCT (2005) assessed the efficacy of RF facet joint denervation compared to a sham procedure. The author concluded that there were no differences between the two groups except a significant improvement in VAS scores. NICE concluded that patients should not be referred for any of the following procedures: ▪ intradiscal electrothermal therapy (IDET) ▪ percutaneous intradiscal radiofrequency thermocoagulation (PIRFT) ▪ radiofrequency facet joint denervation.	**Literature review:** Systematic review **Grading system:** NICE **Key references:** Leclaire 2001, Nath 2008, van Wijk 2005
American Society of Anaesthesiologists (ASA) Task Force (2010)[10] **US**	**Indications:** Chronic pain management **Population:** Not specified	*Practice guidelines for chronic pain management. An updated report by the American Society of Anesthesiologists Task Force on chronic pain management and the American Society of Regional Anesthesia and Pain Medicine:* RF ablation:_Meta-analytic findings from RCTs comparing conventional (e.g. 80°C) or thermal (e.g. 67°C) RF ablation of medial branches with sham controls report lower pain scores for assessment periods of two to six months after the procedure for patients with low back pain (Category A1 evidence). An RCT of conventional radiofrequency ablation for patients with neck pain and no radiculopathy reports pain relief for up to six months after the procedure (Category A3 evidence). One RCT comparing water-cooled radiofrequency with sham control for chronic sacroiliac joint pain	**Literature review:** Systematic review **Grading system:** Task Force **Key references:** Not included

		reports lower pain scores in the radiofrequency ablation group for up to three months (Category A3 evidence). One RCT reported no difference in lumbar radicular pain when thermal radiofrequency ablation of the dorsal root ganglion was compared with sham control (Category C2 evidence). Consultants, ASA members, and ASRA members strongly agreed that conventional (e.g. 80°C) or thermal (e.g. 67°C) radiofrequency ablation of the medial branch nerves to the facet joint should be performed for neck or low back (medial branch) pain._They were equivocal as to whether water-cooled radiofrequency ablation should be used for chronic sacroiliac joint pain. Consultants disagreed and ASA members and ASRA members were equivocal with regard to whether conventional or thermal radiofrequency ablation of the dorsal root ganglion should be used for the treatment of lumbar radicular pain.	
American Pain Society (2009)[35] **US**	**Indications:** Low back pain **Population:** Not specified	*Guideline for the evaluation and management of low back pain. Evidence Review by American Pain society:* For facet joint pain, six placebo-controlled trials of RF denervation were difficult to interpret. One trial (n=40) used controlled facet joint blocks to select patients and an ablation technique believed to be optimal (Hooten) found RF denervation superior to sham treatment by -1.4 to -1.6 points (0 to 10 VAS scale) for improvement in generalised, back, and leg pain after 6 months, but the difference was not statistically significant for back pain (the main symptom thought to be associated with facet pain). Baseline pain scores in RF denervation group averaged 1.6 points higher ($p<0.05$ for differences) than in the sham group, which suggests unsuccessful randomisation and could be associated with regression to the mean or differential potential for improvement. Furthermore, final pain scores in both groups were identical. Three other trials met criteria to be classified as higher quality but used uncontrolled diagnostic facet joint blocks to select patients, may have used suboptimal techniques (Hooten, Bogduk, Gofeld), and reported conflicting results. One trial (n=30) found RF denervation associated with moderately greater improvement in mean VAS pain (-2.4 vs. -0.4 on a 0 to 10 scale, $p<0.05$) and ODI scores (-11.1 vs. +1.7, $p<0.05$) versus sham through two months (van Kleef). RF denervation also associated with greater likelihood of experiencing at least a two point reduction in VAS pain score and greater than 50% improvement in global effect at eight weeks (67% vs. 37.5%, $p=0.003$) and 12 months (46.7% vs. 12.5%, $p=0.02$). The second trial (n=70) found RF denervation superior to sham treatment for mean improvement in RDQ scores at four weeks (-8.4 vs. -2.2, $p=0.05$), but there were no statistically significant differences in ODI or VAS pain scores. At twelve weeks, the difference in RDQ scores was no longer present. The third trial (n=82) found no differences between radiofrequency and sham intervention on any outcome (van Wijk).	**Literature review:** Systematic review **Grading system:** Operationalisation of Oxman criteria, adapted from Furlan et al **Key references:** Van Wijk 2005, van Kleef 1999, Nath 2008, Tekin 2007
American Pain Society (2009)[9] **US**	**Indications:** Low back pain **Population:** Not specified	*Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the American Pain Society:* There was insufficient evidence to adequately evaluate benefits of radiofrequency denervation for non-radicular low back pain. Trials of RF denervation (Leclaire, Nath, van Kleef, van Wijk) reported inconsistent results between small numbers of higher quality trials and (in the case of radiofrequency denervation) technical or methodologic shortcomings, (Hooten) making it difficult to reach conclusions about benefits.	**Literature review:** Systematic review **Grading system:** Adapted from methods developed by the US Preventive Services Task Force **Key references:**

			Leclaire, Nath, van Kleef, van Wijk, Hooten
American Pain Society (2009)[34] **US**	**Indications:** Low back pain **Population:** Not specified	*Nonsurgical interventional therapies for low back pain: a review of the evidence for an American Pain Society clinical practice guideline:* Few nonsurgical interventional therapies, including RF ablation, for low back pain have been shown to be effective in randomised, placebo-controlled trials.	
Towards Optimised Practice (2011)[11] **Canada**	**Indications:** Low back pain **Population:** Adults >18 years.	*Guideline for the evidence-informed primary care management of low back pain:* The following injection therapies may be beneficial for carefully selected patients with a clinical diagnosis of pain originating from the lumbar facet joints: Medial branch neurotomy (studies demonstrate pain relief lasting longer than three months). The clinical diagnosis of facet joint pain lacks specificity and may be best determined by a trained spinal care specialist. The most commonly reported adverse events are: Facet joint interventions: haematoma, steroid side effects, accidental dural puncture and infection. Radiofrequency denervation: increased pain (usually temporary) due to neuritis, and cutaneous dysaesthesias.	**Literature review:** Systematic review **Grading system:** – **Key references:** –

Study	Description	Sample size (n)	Finding
van Zundert et al (2012)[40] **Belgium**	Meta-analysis	N=6 RCTs	*Radiofrequency Treatment of Facet-related Pain: Evidence and Controversies:* The results of RCTs on the use of radiofrequency treatment of facet joint pain demonstrate that good patient selection is imperative for good clinical outcome. They suggest one block of the ramus medialis of the ramus dorsalis before RF treatment.
Niemisto et al (2010)[39] **Finland**	Cochrane review	N=3 RCTs	*Radiofrequency denervation for neck and back pain (Review):* The review found that RF denervation can provide short-term pain relief for a small proportion of people with specific joint problems in the neck. There is conflicting evidence about effects for low-back joint pain, and some evidence that it does not relieve pain from low-back disc problems (based on three RCTs, van Kleef, Gallagher, Leclaire).
Van Kleef (2010)[6] **Netherlands**	Systematic review		*12. Pain originating from the lumbar facet joints:* The 'gold standard' for treating facetogenic pain was RF treatment (1 B+) at the time. The evidence supporting intra-articular corticosteroids was limited; hence, this should be reserved for those individuals who do not respond to RF treatment (2 B±).

Bogduk et al (2009)[36] **US**	Narrative review		*A narrative review of lumbar medial branch neurotomy for the treatment of back pain:* Aim of study was to demonstrate how rationale and efficacy of lumbar medial branch neurotomy depends critically on correct selection of patients and use of surgically correct technique. Three studies, commonly accepted as evidence of lack of effectiveness, were not valid tests of lumbar medial branch neurotomy because of errors in selection of patients or errors in surgical technique, or both. Two descriptive studies and three controlled studies that used valid or acceptable techniques consistently showed that lumbar medial branch neurotomy had positive effects on pain and disability. All valid RCTs showed medial branch neurotomy to be more effective than sham treatment. Negative results have been reported only in studies that selected inappropriate patients or used surgically inaccurate techniques. All valid studies showed positive outcomes that cannot be attributed to placebo. Inappropriate conclusions have been drawn by systematic reviews that misrepresent invalid studies as providing evidence against the efficacy of lumbar medial branch neurotomy.
Datta et al (2009)[37] **US**	Systematic review		*Systematic assessment of diagnostic accuracy and therapeutic utility of lumbar facet joint interventions:* Based on USPSTF criteria, evidence showed Level I or II-1 for diagnostic facet joint nerve blocks. Based on the review of included therapeutic studies, Level II-1 to II-2 evidence was indicated for lumbar facet joint nerve blocks with indicated level of evidence of Level II-2 to II-3 for lumbar radiofrequency neurotomy (Evidence obtained from at least one properly designed small diagnostic accuracy study; II-2: Evidence obtained from at least one properly designed small diagnostic accuracy study; II-3: Evidence obtained from diagnostic studies of uncertainty).
Hooten et al (2005)[38] **US**	Systematic review	Three RCTs, two systematic reviews	*Radiofrequency Neurotomy for Low Back Pain: Evidence-Based Procedural Guidelines:* Substantial procedural shortcomings were identified in all three RCTs. In the systematic reviews, these procedural limitations were not accounted for by the quality assessment of study design which resulted in an inaccurate estimate of clinical effectiveness. Analysis using likelihood ratios showed that screening criteria could increase the probability of zygapophysial joint pain before performing diagnostic blocks. Similar analysis showed that comparative medial branch blocks, rather than single blocks, must be used before RF neurotomy. Anatomical studies demonstrated that the shorter distal compared with the circumferential radius of the RF lesion necessitates placement of the electrode parallel to the course of the nerve along the base of the superior articular process. The evidence-based procedural guidelines provide consistent criteria for multi-site studies that could enrol a sufficiently large homogenous study cohort.

RCTs	Scope	Finding
Nath et al (2008)[44] **US**	RCT N=40 patients	*Percutaneous lumbar zygapophysial (facet) joint neurotomy using radiofrequency current, in the management of chronic low back pain: a randomised double-blind trial.* Percutaneous RF neurotomy conducted in patients with chronic low back pain (20 active and 20 controls). The active treatment group showed statistically significant improvement in back and leg pain, but also back and hip movement as well as the sacroiliac joint test. Pre-operative sensory deficit and weak or absent ankle reflex normalised ($P < 0.01$) and ($P < 0.05$), respectively. There was significant improvement in quality of life variables, global perception of improvement, and generalised pain. The improvement seen in the active group was significantly greater than that seen in the placebo group with regard to all the above-mentioned variables. None of our patients had any complication other than transient post-operative pain that was easily managed. Study indicates that RF facet denervation is not a placebo and could be used in the treatment of carefully selected patients with chronic low back pain.
Van Wijk (2005)[45] **Australia**	RCT N=81 patients	*Radiofrequency denervation of lumbar facet joints in the treatment of chronic low back pain: a randomized, double-blind, sham lesion-controlled trial:* Combined outcome measure showed no differences between RF facet joint denervation (n=40; success 27.5%) and sham (n=41; success 29.3%) (P=0.86). The VAS in both groups improved (P<0.001). Global perceived effect improved after RF facet joint denervation (P<0.05). The other secondary outcome parameters showed no significant differences. Relevant costs were evaluated. The author concluded that the combined outcome measure and VAS showed no difference between RF and sham, though in both groups, significant VAS improvement occurred. The global perceived effect was in favour of RF. In selected patients, RF facet joint denervation appears to be more effective than sham treatment.
Leclaire (2001)[43] **Canada**	RCT N=70 patients	*Radiofrequency facet joint denervation in the treatment of low back pain: a placebo-controlled clinical trial to assess efficacy:* At four weeks, the Roland-Morris score had improved by a mean of 8.4% in the neurotomy group and 2.2% in the placebo group, showing a treatment effect of 6.2% ($P = 0.05$). At four weeks, no significant treatment effect was reflected in the Oswestry score (0.6% change) or the visual analog pain score (4.2% change). At 12 weeks, neither functional disability, as assessed by the Roland-Morris scale (2.6% change) and Oswestry scale (1.9% change), nor the pain level, as assessed by the visual analog scale (-7.6% change), showed any treatment effect. The authors concluded that although RF facet joint denervation may provide some short-term improvement in functional disability among patients with chronic low back pain, the efficacy of this treatment has not been established.
Civelek et al (2012)[41] **Turkey**	RCT N=100 patients	*Comparison of effectiveness of facet joint injection and radiofrequency denervation in chronic low back pain:* The author recommends that the first choice should be the facet joint injection and if pain reoccurs after a period of time or injection is not effective, RF procedure should be used for the treatment of chronic lumbar pain. Comparisons indicated that therapeutic benefits of injections occurred immediately following the injection. However, the effect of RF begins a few weeks later. None of the RF patients needed surgery after the procedure in the long-term follow-up period.
Cohen et al (2010)[42] **US**	RCT N=151 patients	*Multicenter, randomized, comparative cost-effectiveness study comparing 0, 1, and 2 diagnostic medial branch (facet joint nerve) block treatment paradigms before lumbar facet radiofrequency denervation:* Group 0 (RF denervation) based solely on clinical findings; group 1 underwent denervation contingent on a positive response to a single diagnostic block; and group 2 proceeded to denervation only if they obtained a positive response to comparative blocks done with lidocaine and bupivacaine. A positive outcome was predesignated as > or =50% pain relief coupled with a positive global perceived effect persisting for three months. In group 0, 17 patients (33%) obtained a successful outcome at three months versus eight patients (16%) in group 1 and 11 (22%) patients in group 2. Denervation success rates in groups 0, 1, and 2 were 33, 39, and 64%, respectively. Pain scores

		and functional capacity were significantly lower at three months but not at one month in group 2 subjects who proceeded to denervation compared with patients in groups 0 and 1. The costs per successful treatment in groups 0, 1, and 2 were $6,286, $17,142, and $15,241, respectively. Using current reimbursement scales, these findings suggest that proceeding to radiofrequency denervation without a diagnostic block is the most cost-effective treatment paradigm.

UK PCT* / US examples of thresholds	Scope	Threshold	Evidence
Bedfordshire and Herefordshire PCT[56] **UK**	**Indications:** Chronic back pain **Population:** >18 years old	PCTs will fund thermal RF controlled denervation of medial branch of dorsal rami of lumbar and cervical facet joints (medial branch neurotomy) if: ■ patients aged over 18 ■ non-radicular lumbar (all levels) or cervical (C3-4 and below) facet joint pain ■ failure of six months of non-invasive therapy, such as medication and physiotherapy and bed rest ■ average pain levels of ≥6 on scale of 0 to 10. Levels of pain must be assessed using a validated tool, e.g. McGill Pain Questionnaire, Pain Visual Analogue Score (VAS) ■ radiological imaging to rule out any correctable structural lesion, e.g. MRI ■ at least two anaesthetic diagnostic blocks, one of which must be of medial branch of dorsal ramus innervating the target facet joint, with at least 80% reduction in pain following each block during activities that normally generate pain. The pain relief must be consistent with the expected duration of the anaesthetic block ■ all procedures must be performed under fluoroscopy (x-ray guidance). PCTs will not fund cryoneurolysis or laser denervation. PCTs will not fund this procedure in patients with facet joint pain associated with a neurological deficit, radiculopathy or overt disc herniation, metastatic disease, patients awaiting back surgery, multiple, focal or chronic pain syndromes. PCTs will fund one injection per side per level, i.e. one facet neurotomy at the same side at the same level or two joint levels unilaterally or bilaterally. PCTs will not fund retreatment at the same location unless at least six months have elapsed since prior treatment. If more than one region are involved all regions should be treated at the same time, provided all procedures are performed safely. Cervical and thoracic are considered as one region and lumbar and sacral are considered as one region.	Laxmaiah 2009, Gofeld 2007.
NHS Black Country Cluster PCT[59] **UK**	**Indications:** Chronic back pain **Population:** Not specified	Unless all of the following criteria are met RF and electrothermal ablation for chronic low back pain will not normally be funded: Minimum Eligibility Criteria: ■ pain originating in the cervical, thoracic, or lumbar spinal regions lasting more than 12 months ■ pain documented as significantly interfering with daily life (e.g. loss of function > 50% on EuroQol or BPI tool), despite maximal conservative management (physiotherapy guided exercise, maximal analgesia and muscle	NICE CG88

		relaxants, psychological treatment) AND Symptoms are NOT consistent with identifiable pathology including disc herniation, spondylolisthesis, spinal stenosis AND ■ absence of any neurologic deficit AND ■ it is recommended by a dedicated pain management clinician AND ■ it is part of a comprehensive/dedicated pain management programme (they will not be funded as standalone treatments) AND ■ two diagnostic medial branch nerve blocks, provided under a standard protocol that alternates long- and short-acting anaesthetic blocks, produce symptom relief physiologically consistent with medial nerve branch pathology. Limitations: For the purposes of this policy, a procedure consists of one or more ablations during a single visit. Procedures are limited to two per year.	
South West London PCT[60] **UK**	**Indications:** Cervical and lumbar back pain **Population:** >18 years old	PCTs will fund thermal RF controlled denervation of the medial branch of the dorsal rami of the lumbar and cervical facet joints (medial branch neurotomy) in the following circumstances: ■ patients aged over 18 AND ■ non-radicular lumbar (all levels) or cervical (C3-4 and below) facet joint pain AND ■ failure of one year of non-invasive therapy, such as medication and physiotherapy and bed rest AND ■ radiological imaging to rule out any correctable structural lesion, e.g. MRI AND ■ at least two anaesthetic diagnostic blocks, one of which must be of the medial branch of the dorsal ramus innervating the target facet joint, with at least 80% reduction in pain following each block during the activities that normally generate pain. The pain relief must be consistent with the expected duration of the anaesthetic block AND ■ all procedures must be performed under fluoroscopy (x-ray guidance) ■ thermal radiofrequency denervation is provided as part of a comprehensive pain management programme. PCTs will not fund cryoneurolysis or laser denervation. PCTs will fund up to three facet denervations on one occasion. PCTs will not fund re-treatment at the same location unless at least six months have elapsed since prior treatment. Evidence of effectiveness of the treatment of facet joint pain associated with a neurological deficit, radiculopathy or overt disc herniation, metastatic diseases, patients awaiting back surgery or patients with multiple, focal or chronic pain syndromes is limited due to the exclusion criteria of clinical trials.	NICE CG88, ASIPP[12], APS[34]
Surrey PCT **UK**	**Indications:** Cervical and lumbar back pain **Population:** >18 years old	RF facet joint denervation of the medial branch of the dorsal rami of the lumbar and cervical facet joints (medial branch neurotomy) will be funded in the following circumstances: ■ patients aged over 18 ■ non-radicular lumbar (all levels) or cervical (C3-4 and below) facet joint pain ■ failure of an appropriate trial of non-invasive therapy, such as medication and physiotherapy	NICE CG 88

		▪ one anaesthetic diagnostic block, which must be of the medial branch of the dorsal rami innervating the target facet joint. A significant reduction in pain following the block during activities that normally generate pain should be demonstrated and recorded. The pain relief must be consistent with the expected duration of the anaesthetic block ▪ all procedures must be performed under fluoroscopy (x-ray guidance) ▪ thermal radiofrequency denervation is provided as part of a comprehensive pain management programme. Cryoneurolysis or laser denervation will not be funded. Up to four facet joint denervations on one occasion (one treatment episode) will be funded. Re-treatment at the same location will not be funded, unless at least twelve months have elapsed since prior treatment. Procedure will not be funded for early management of persistent non-specific low back pain (NICE CG 88).	
Inland Empire Healthcare (2012)[57] **US**	**Indications:** Cervical and lumbar back pain **Population:** Not specified	*Percutaneous radiofrequency neurotomy:* Considered medically necessary for treatment of members with intractable cervical or lumbar back pain with or without sciatica in the outpatient setting when all of the following are met: ▪ member has experienced severe pain limiting activities of daily living for at least six months ▪ member has had no prior spinal fusion surgery ▪ neuroradiologic studies are negative or fail to confirm disc herniation ▪ member has no significant narrowing of the vertebral canal or spinal instability requiring surgery ▪ member has tried and failed conservative treatments such as bed rest, back supports, physiotherapy, correction of postural abnormality, as well as pharmacotherapies (e.g., anti-inflammatory agents, analgesics and muscle relaxants) and ▪ trial of facet joint injections has been successful in relieving pain, with at least a 50% reduction of pain ▪ at least six months has elapsed since prior denervation treatment (per side, per anatomical spine level).	Van Wijk 2005, Leclaire 2001, van Kleef 1999, Guerts 2003, Nath 2008
Emblem Health (2012)[61] **US**	**Indications:** Cervical, thoracic, lumbar spinal pain **Population:** Not specified	*Radiofrequency ablation for cervical, thoracic or lumbar spinal pain:* Members with moderate to severe cervical, thoracic or lumbar spinal pain are eligible for coverage of RF ablation when the following criteria are met: ▪ pain secondary to facet joint origin, as evidenced by the absence of nerve root compression and radicular pain ▪ pain refractory for six month period and failed to respond to three months of conservative management (e.g. nonsteroidal anti-inflammatory/opioid medications, chiropractic therapy/physical therapy and a home exercise programme) ▪ demonstration of symptom relief secondary to a trial of two controlled diagnostic medial branch blocks provided under a standard alternating protocol of alternating short and long-acting anaesthetic blocks ▪ no history of spinal fusion surgery in the vertebral level being treated. Limitations/Exclusions: As results may be transient, a repeat RFA is considered medically necessary when a prior treatment has been	E.g. Chou 2010, Boswell 2005, Hooten 2005, Niemisto 2002,

		successful as follows: ■ ≥ six month treatment lapse per level per side. ■ Achievement of ≥ 50% pain reduction in conjunction with functional improvement. The following treatment protocols are not considered to be medically necessary: ■ one treatment per level per side within a six-month period. ■ two treatments per year. Long-term, repeated or maintenance. (Requests for treatment beyond the first year will be medical director-reviewed) Note: RFA performed to the medial branch nerves for a maximum of three facet levels, or denervation of five spinal medial branches unilaterally will be allowed on a single visit.	
AETNA (2013)[55] **US**	**Indications:** Cervical or back pain **Population:** Not specified	*Back Pain – Invasive Procedures:* Non-pulsed radiofrequency facet denervation is considered medically necessary for treatment of members with intractable cervical or back pain with or without sciatica in the outpatient setting when all of the following are met: ■ member has experienced severe pain limiting activities of daily living for at least six months AND ■ member has had no prior spinal fusion surgery AND ■ neuroradiologic studies are negative or fail to confirm disc herniation AND ■ member has no significant narrowing of the vertebral canal or spinal instability requiring surgery AND ■ member has tried and failed conservative treatments such as bed rest, back supports, physiotherapy, correction of postural abnormality, as well as pharmacotherapies (e.g. anti-inflammatory agents, analgesics and muscle relaxants) AND ■ trial of facet joint injections has been successful in relieving the pain. Non-pulsed radiofrequency facet denervation is considered experimental and investigational for all other indications because its effectiveness for indications other than the ones listed above has not been established. Only one treatment procedure per level per side is considered medically necessary in a six month period. Aetna considers pulsed radiofrequency experimental and investigational for all indications, including those in the following list, because its effectiveness has not been established: ■ chronic pain following inguinal herniotomy, discogenic pain, facet and sacroiliac joint arthropathy, headache, low back pain, lower extremity neuralgia, lumbo-sacral radicular syndrome, myofascial or neuromatous pain, neck pain, occipital neuralgia, osteoarthritis of the knee, premature ejaculation, pudendal neuralgia, reflex sympathetic dystrophy/complex regional pain syndrome, sacroiliac joint pain, shoulder pain, testicular pain (orchialgia), trigeminal neuralgia, zygapophysial joint pain.	E.g. American Society of Anesthesiologists Task Force[10], Niemisto 2003, Van Zundert 2003

*Note: In April 2013, it was announced that the UK PCTs are being abolished; however they are being replaced by other new organisations including clinical commissioning groups. The PCT thresholds may still apply.

Appendix 2 – Cost-effectiveness studies

Study	Type	Approach / Findings
Cohen et al (2010)[42] **US**	Comparative CE	*Multicenter, randomized, comparative cost-effectiveness study comparing 0, 1, and 2 diagnostic medial branch (facet joint nerve) block treatment paradigms before lumbar facet radiofrequency denervation:* Group 0 (RF denervation) based solely on clinical findings; group 1 underwent denervation contingent on a positive response to a single diagnostic block; and group 2 proceeded to denervation only if they obtained a positive response to comparative blocks done with lidocaine and bupivacaine. The costs per successful treatment in groups 0, 1, and 2 were $6,286, $17,142, and $15,241, respectively. Using current reimbursement scales, these findings suggest that proceeding to radiofrequency denervation without a diagnostic block is the most cost-effective treatment paradigm.
Gupta et al (2012)[47] **EU**	Survey of costs	*E-survey of European pain medicine practice:* This survey was undertaken to explore the variation in the functional constitution of pain clinics in Europe. Eighty-two pain practitioners (13 countries, mainly the UK) responded. It noted that two-thirds of respondents reported the cost of 4-joint RF lumbar denervation to be less than €1,500.
Bogduk and Holmes (2000)[46] **Australia**		*Controlled zygapophysial joint blocks: the travesty of cost-effectiveness:* The cost of a medial branch block for diagnosis of zygapophysial joint pain ranged from $173 to $400 for two nerves and including a surcharge, fluoroscopy, and 'consumables' across three payers in one state; and from $793 to $955 for two nerves and including a facility fee across three payers in another state. Similarly, the cost of treatment with radiofrequency ablation ranged from $248 to $499 for two nerves and including a surcharge, fluoroscopy, and 'consumables' across three payers in one state and from $1,227 to $1,310 for two nerves and including a facility fee across three payers in another state.

Published by the Health Information and Quality Authority.

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