

Fasetliigeste denerveerimine (RFA) kui ravi meetod sisaldub **NICE Guideline (Low back pain and sciatica in over 16s: assessment and management, 2016)**

Soovitud:

1.3.2 Consider referral for assessment for radiofrequency denervation for people with chronic low back pain when:

- non-surgical treatment has not worked for them **and**
- the main source of pain is thought to come from structures supplied by the medial branch nerve **and**
- 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.

1.3.3 Only perform radiofrequency denervation in people with chronic low back pain after a positive response to a diagnostic medial branch block.

1.3.4 Do not offer imaging for people with low back pain with specific facet joint pain as a prerequisite for radiofrequency denervation.

<https://www.nice.org.uk/guidance/ng59/chapter/Recommendations>

Efektiivsus:

Radiofrequency denervation compared with placebo/sham for low back pain

Evidence from 4 studies demonstrated clinical benefit in pain for radiofrequency denervation compared to placebo/sham at both the short and long term follow-ups of less than and greater than 4 months (low to moderate quality, n=160). In contrast there was no difference in function between treatments at any time point. Conflicting evidence from 1 study for quality of life at less than 4 months follow up showed clinical benefit for radiofrequency denervation compared to placebo/sham for the SF-36 domains of general health and vitality. Radiofrequency denervation was inferior to sham for the domains of mental health, pain and social function. There was no difference between treatments for the domain physical function (low quality, n=81). Evidence from a single study reporting adverse events at less than 4 months follow up demonstrated an increase in adverse effects for radiofrequency denervation in terms of the number of patients with moderate or severe treatment related pain (low quality, n=79). There was no difference in other adverse events (change of sensibility and loss of motor function) at short term follow up when

radiofrequency denervation was compared to placebo/sham in the same study (very low quality). Additionally when compared with placebo/sham, benefit for radiofrequency denervation in responders to pain reduction measured by global perceived effect was demonstrated by 2 studies at both the less than and greater than 4 months follow up time points although this was not seen for pain reduction measured by VAS at less than 4 months reported by a single study (low quality, n=111).

Radiofrequency denervation versus medial branch block

Evidence from a single study demonstrated clinical benefit in terms of pain for radiofrequency denervation compared to medial branch blocks at both the short and long term follow-ups of less than and greater than 4 months (very low quality, n=100).

Economic

One cost-consequence analysis found that radiofrequency denervation was more costly and more effective (£186 more per patient, SF-36 general health and vitality and global perception of reduction in back pain and pain responder criteria) compared to sham for treating low back pain (with or without sciatica). This analysis was assessed as partially applicable with potentially serious limitations. One original economic model found that radiofrequency denervation was cost effective compared to usual care for treating low back pain suggestive of facet joint origin that has not resolved despite non-invasive management (ICER £11,178). This analysis was assessed as partially applicable with potentially serious limitations

Riski/kasu suhe

Radiofrequency denervation versus placebo/sham

Pain relief (VAS) was seen in studies in both the short term (up to 4 months) and long term (greater than 4 months). However, there was no clinical benefit seen in terms of function (for both ODI and RMDQ). The GDG noted that the baseline ODI scores reported in the study informing this outcome were different between groups and both groups were in the 'minimal disability' range post intervention. The RMDQ scale reported by 1 study was not reported in a standard way and had been converted to a 0-100 scale by the authors, with higher scores indicating benefit, rather than the standard 0-24 scale where higher scores indicate decline in function. Therefore the GDG were not able to place much confidence in these outcomes. For quality of life (SF-36), evidence from a single study showed clinical benefit for the domains of general health and vitality. However, in terms of physical function, the benefit was in favour of the placebo group. It was noted however that there were large baseline differences for physical function between the intervention and sham groups, with the intervention groups being 10 points worse at baseline, and that this data showing benefit to the placebo group was not considered reliable. The GDG therefore agreed that the benefits seen in quality of life outweighed the harm. The GDG also noted that 1 study selectively reported domains of SF-36; for role physical and role emotional scales, the results were reported in terms of 'number of patients

who went up or down by 1 or more classes' rather than mean differences, which is not standard reporting of SF-36 data and therefore were not able to be included in this systematic review. The GDG noted there was limited data on adverse events from the included evidence, and they considered it alongside their expert opinion and knowledge to inform decision making. Only 1 study reported adverse event data, and reported no adverse events (in terms of complications) in either the placebo or the radiofrequency arms. However the GDG noted that there was clinically significant harm for the radiofrequency group in terms of treatment-related pain (graded as moderate/severe) at the short term. It was noted that there was some treatment related harm in the sham group as well, so both groups experienced pain that was considered to be related to the procedure. Data were only reported for less than 4 months but the GDG noted that one would not expect any treatment-related pain to occur beyond 4 months. The study reported 2 adverse events (5%) which were change of sensibility (dysaesthesia or allodynia) in the radiofrequency denervation Low back pain and sciatica in over 16s: assessment and management Radiofrequency denervation for facet joint pain © National Institute for Health and Care Excellence 2016. 62 group. The GDG noted that these particular adverse events were important outcomes to the patient, although the event rate in the study was very small, it was higher than expected (based on the GDG's clinical experience). However the size of the study itself was very small (n=79) and only reported this outcome at less than 4 months. The group therefore agreed that although the effect size for these adverse events was considered clinically important, because of the concerns noted, they did not have confidence in extrapolating this data to clinical practice. The GDG also considered that although allodynia may occur, it is likely to only affect a small number of patients. They concluded that as the risk is low and the 5% seen in the evidence is higher than would be expected, the benefits observed in terms of pain and quality of life outweighed this risk of harm. The study additionally reported 'loss of motor function' as an adverse event. The event rate was extremely small (zero events versus 1 event in the radiofrequency group and placebo/sham group respectively). This was considered as clinically important, but again due to the study having a small sample size, short duration of follow up, and low event rate, this risk of harm was also not considered to outweigh the benefits. The GDG considered that although there was limited data from the included studies on adverse events, there are no case reports that the GDG are aware of reporting serious complications (such as paralysis or death) from radiofrequency denervation. Several studies looked at analgesic use following the procedure at less than four months. There was no detail provided regarding number of treatments per day or what the baseline medication intake was. The GDG considered that there was no clinically important difference between groups, but this could not be accurately interpreted from the data reported. Patient perception of their global improvement of analgesic use rated on a 0-6 scale, at greater than 4 months was reported by 1 study. This was noted as a small effect on a scale that was difficult to interpret or determine whether there was benefit or not and did not consider it informative for decision making. The GDG considered the evidence for responder criteria ($\geq 50\%$ reduction in pain) which

was reported by several studies. There was clinical benefit at both short and long term follow up for global perception of reduction in back pain and pain; however there was no difference in the short-term in reported peak pain on VAS (median of 4 measurements). It was noted that this was from the same study, but as the study only reported 'peak pain' the global perception of pain reduction may be more informative. The GDG noted that 2 of the studies included in the review did not include a true diagnostic medial branch block and this may have resulted in an unselected patient population. The majority of studies used 1 diagnostic medial branch block. The GDG were mindful that had all studies included a true medial branch block, the effect size may have been larger.

Radiofrequency denervation versus medial branch block

One study compared radiofrequency denervation with medial branch block (with a local anaesthetic and steroid). The GDG noted that the study only looked at 2 outcomes relevant to this review; pain and quality of life assessed by EQ-5D. There were no data reported for adverse events. Pain assessed on a VNS was lower in the group receiving radiofrequency denervation at both short and long-term follow-ups, and this reduction was considered clinically important. The quality of life data (EQ-5D) showed no clinical difference between interventions but the GDG noted that the EQ-5D data was incompletely reported, and had not been analysed in the typical format that is appropriate for EQ-5D (i.e. summarised as a scale of 0-1; it was not weighted or in a linear scale). They were therefore unable to interpret the EQ-5D data and so it was not considered to be useful for decision-making.

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https://www.bcbswny.com/content/dam/COMMON/non-secure/provider/Protocols/F/prov_prot_701116.pdf

Effektiivsus:

For individuals who have suspected facet joint pain who receive diagnostic medial branch blocks, the evidence includes a systematic review of 17 diagnostic accuracy studies, a small randomized trial, and several large case series. Relevant outcomes are test accuracy, other test performance measures, symptoms, and functional outcomes. There is considerable controversy about the role of these blocks, the number of positive blocks required, and the extent of pain relief obtained. Studies have reported the use of single or double blocks and at least 50% or at least 80% improvement in pain and function. This evidence has suggested that there are relatively few patients who exhibit pain relief following two nerve blocks, but that these select patients may have pain relief for several months following RF denervation. Other large series have reported prevalence and false-positive rates following controlled diagnostic blocks, although there are issues with the reference standards used in these studies because there is no criterion standard for diagnosis of

facet joint pain. There is level I evidence for the use of medial branch blocks for diagnosing chronic lumbar facet joint pain and level II evidence for diagnosing cervical and thoracic facet joint pain. The evidence available supports a threshold of at least 75% to 80% pain relief to reduce the false-positive rate. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have facet joint pain who receive radiofrequency ablation, the evidence includes a systematic review of randomized controlled trials (RCTs). Relevant outcomes are symptoms, functional outcomes, quality of life, and medication use. While evidence is limited to a few RCTs with small sample sizes, RF facet denervation appears to provide at least 50% pain relief in carefully selected patients. Diagnosis of facet joint pain is difficult. However, response to controlled medial branch blocks and the presence of tenderness over the facet joint appears to be reliable predictors of success. When RF facet denervation is successful, repeat treatments appear to have similar success rates and durations of pain relief. Thus, the data indicate that, in carefully selected individuals with lumbar or cervical facet joint pain, RF treatments can result in improved outcomes. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have facet joint pain who receive therapeutic medial nerve branch blocks or alternative methods of facet joint denervation the evidence includes uncontrolled case series and randomized trials without a sham control. Relevant outcomes are symptoms, functional outcomes, quality of life, and medication use. Pulsed RF does not appear to be as effective as conventional RF denervation, and there is insufficient evidence to evaluate the efficacy of other methods of denervation (e.g., alcohol, laser, cryodenervation) for facet joint pain or the effect of therapeutic medial branch blocks on facet joint pain. The evidence is insufficient to determine the effects of the technology on health outcomes.

Kirjandus

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39. National Government Services, Inc. (Primary Geographic Jurisdiction 06 & K - Illinois, Minnesota, Wisconsin, Connecticut, New York - Entire State, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont) Local Coverage Determination (LCD): FACET JOINT Injections, Medial Branch Blocks, and FACET JOINT Radiofrequency Neurotomy (L35936), Revision Effective Date for services performed on or after 10/01/2015.

Sakroiliakaal liiduse testblokaad ja RFA

SI joint injections with local anesthetic and corticosteroids may provide good pain relief for periods of up to 1 year. It is assumed that intra - articular injections would produce better results than periarticular infiltrations. Yet, periarticular infiltrations were demonstrated to provide good pain relief in short - term follow - up in 2 double - blind studies, 24,25 indicating the importance of extra - articular sources of SI pathology. 29 – 31 Controlled studies support the assertion that both intra - and extra - articular injections may be beneficial. Luukkainen et al. 30 randomized 24 patients to receive either peri - articular corticosteroid with local anesthetic (n = 13), or local anesthetic and saline (n = 11). One month after the intervention, visual analog scale (VAS) pain scores had decreased significantly in the corticosteroid group compared with the control patients. Maugars et al. 32 treated 13 SI joints in 10 patients. Intra - articular corticosteroids were injected into 6 SI joints, while the remaining 7 joints received physiological saline solution. After 1 month, pain reduction of > 70% was noted in 5 of the 6 SI joints treated with corticosteroid, whereas no benefit was noted in the placebo group. In all control patients and 2 in the treatment group who had short - term symptom palliation, a repeat corticosteroid injection was performed. After 1, 3, and 6 months, significant pain reduction was observed in 86%, 62%, and 58% of patients, respectively.

The efficacy of RF treatment of the SI joint is illustrated by several prospective observational, 33,34 retrospective studies 35 – 37 and 1 randomized controlled study. 38 However, the selection criteria, definition of success, and RF parameters (ie, temperature, duration, and location of RF treatment) have varied widely between studies. Gevargez et al. 34 performed three 90 ° C lesions in the ligamentum sacroiliacum posterius and 1 targeting the L5 ramus dorsalis. In contrast, Ferrante et al. 35 performed multiple bipolar intra - articular lesions at 90 ° C. Cohen and Abdi 36 performed single 80 ° C lesions at the level of the L4 – L5 rami dorsales and the S1 to S3 (or S4) rami laterales of the rami dorsales. Yin et al. 37 applied a similar technique, except that they excluded the L4 ramus dorsalis, and selected more caudal levels based on concordant sensory stimulation. Burnham and Yasui 33 performed bipolar RF strip lesions lateral to the foramen sacrale posterius and a monopolar

RF treatment at the level the L5 ramus dorsalis. More recently, Cohen et al. 39 investigated which demographic and clinical variables could be used to predict SI joint RF treatment outcome. In multivariate analysis, pre - procedure pain intensity, age 65 years or older, and pain referral below the knee were all statistically significant predictors of failure. One study reported the use of pulsed RF (PRF) therapy for the treatment of SI joint pain. 40 The L4, L5 rami mediales, and the S1, S2 rami laterales of the rami dorsales were the targets of the therapy. Evidence of a good or excellent result (> 50% and 80% reduction in the VAS, respectively) was obtained in 73% of the patients. The duration of the clinical effect varied from 6 weeks to 32 weeks. Because of variable and extensive innervation of the dorsal SI joint, targeting the nerves innervating the joint with “ classic ” RF methods is sometimes difficult. In 2 double - blind randomized, controlled studies, Dreyfuss et al. 41,42 demonstrated the superiority of multisite, multi - depth sacral lateral branch blocks over single - site, single - depth blocks to anesthetize the SI joint ligaments. However, these studies also demonstrated that lateral branch blocks do not reliably interrupt nociceptive information emanating from the intra - articular portion of the SI joint complex (ie, capsular distension). To circumvent anatomical variations in innervations, some investigators have employed internally cooled RF electrodes, which increase the ablative area by minimizing the effect of tissue charring to limit lesion expansion. In 2008, a retrospective case series 43 and a randomized controlled trial 38 concerning cooled RF treatment of the SI joint were published. In the retrospective trial 3 to 4 months post - treatment, a mean VAS pain score improvement of 2.9 points was noted (7.1 to 4.2). 43 Eighteen patients rated their improvement in pain as either improved or much improved, while 8 reported minimal or no improvement. Cohen et al. 38 performed a randomized placebo - controlled study in which a “ classic ” RF procedure was performed on the L4 and L5 rami dorsales, and a cooled RF treatment of the S1 to S3 rami laterales. One, 3, and 6 months post - treatment, 79%, 64%, and 57% of patients reported $\geq 50\%$ pain relief, respectively. In the placebo group, only 14% experienced significant improvement at 1 month follow - up, and none experienced significant benefit 3 months post - procedure. The additional cost of disposable components needed for a cooled RF procedure should be taken into consideration, because in some countries, no reimbursement exists for this procedure.

Complications Although potential complications of articular injections and RF procedures include infection, hematoma formation, neural damage, trauma to the sciatic nerve, gas and vascular particulate embolism, weakness secondary to extra - articular extravasation, and complications related to drug administration, the reported rate of these complications in SI joint treatment is low. 44 Luukkainen et al. 29,30 reported no complications from peri - articular SI joint injections. For intra - articular injections, Maugars et al. 32 reported only transient perineal anesthesia lasting a few hours and mild sciatalgia (sciatica) lasting 3 weeks, but no information was given as to the number of patients that reported these side effects. For RF treatment of the SI joint, Cohen et al. 38 noted that the majority of 28 patients experienced temporary worsening of pain 5 to 10 days after the procedure that was attributed to procedure - related tissue trauma and temporary neuritis. In a follow - up study, Cohen et al. reported 5 complications out of 77 treated patients. 39 These included 3 cases of temporary paresthesia, 1 superficial skin infection that resolved with antibiotics, and 1 case of hyperglycemia in a

diabetic patient requiring increased insulin use for 3 days. The latter was caused by the corticoid used to prevent procedure - related neuritis; this is a relatively common practice that is, however, not supported by improved outcome in the literature. In their study evaluating PRF of the SI joint, Vallejo et al. observed no complications or worsening of pain. 40,43 Transient buttock dysesthesia or hypoesthesia, and temporary worsening of pain have also been commonly reported in other studies evaluating heat RF. 33,34,37

Kokkuvõte

The SI joint is responsible for 16% to 30% of axial low back complaints and can be difficult to distinguish from other forms of low back pain. Clinical examination and radiological imaging is of limited diagnostic value. The result of diagnostic blocks must be interpreted with caution, because false - positive as well as false - negative results occur frequently. Currently, the majority of scientific evidence points toward intra - articular SI joint infiltrations for short - term improvement. If the latter fail or produce only short - term effects, a combination of cooled and conventional RF treatment of the rami laterales of S1 to S3 (S4) is recommended (2 B +) if available. When this procedure cannot be used, (pulsed) RF procedures targeted at L5 ramus dorsalis and rami laterales of S1 to S3 may be considered (2 C +).

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Kolmikärvä neuralgia

For the elderly patient, treatment using RF treatment of Gasserian ganglion is often preferred over MVD. This is due to the increased morbidity and mortality that are associated with the MVD operation. However, one publication stated that in otherwise healthy people over the age of 70, MVD poses no appreciable increase in risk. (28). MVD is more effective than the Gamma knife treatment. About 60% of the treated patients are painfree for at least 60 months, if the treatment is correctly given. Zakrzewska has indicated that in about 50% of patients, there is sensory loss in the treated branches of the nervus trigeminus. (29) As such, this technique should not be used in secondary trigeminal neuralgia, as seen in postherpetic neuralgia. The only current exception is secondary trigeminal neuralgia due to multiple sclerosis. While pulsed RF treatment would seem to be a reasonable alternative to RF, in the only randomized controlled trial comparing these techniques in the treatment of trigeminal neuralgia, PRF failed to demonstrate efficacy. (30)

Complications The percutaneous RF procedure has a very low morbidity and virtually no mortality. The most prevalent complications are sensory loss in the treated branch or paralysis

of the musculus masseter. In the long term, anesthesia dolorosa, corneal hypoesthesia and keratitis, and temporary paralysis of the third and fourth cranial nerves can occur. A more frequent and less serious complication is hematoma of the cheek, which generally disappears after a few days. Kanpolat et al. reported the results of 25 years experience with 1,600 patients. (31) The above - mentioned complications are: decreased corneal reflex (5.7%), weakness and paralysis of the musculus masseter (4.1%), dysesthesia (1%), anesthesia dolorosa (0.8%), keratitis (0.6%), and temporary paralysis of the third and fourth cranial nerves (0.8%)

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RFA kui ravimeetod soovitatud Helsinki ja Kotka ülikooli ravijuhendites.

KRÜO:

Efektiivsus:

Esimene kirjeldus Nelson et al. 1974

Kuna portatiivsed aparaadid on kasutusel lühikest aega (3-4 aastat), siis antud hetkel puuduvad suured topelt pimedad ja paltcebo kontrollitud uuringud. Kirjanduses palju publikatsioone, mis kirjeldavad praktilist tööd ja selle tulemust. Suur ülevaade Bittmann et al. 2018 koondas kõik, mis hetkel on meetodi ja tulemuste kohta olemas.(Bittman RW, Peters GL, Newsome JM, Friedberg EB, Mitchell JW, Knight JM, Prologo JD. Percutaneous Image-Guided Cryoneurolysis. AJR Am J Roentgenol. 2018 Feb;210(2):454-465. doi: 10.2214/AJR.17.18452. Epub 2017 Dec 8. Review. PubMed PMID: 29220211)

Ohutus:

Percutaneous image-guided CN generally is safe. The available evidence, which is summarized in Tables 1–3, consists of approximately 702 discrete treatments. The exact number of treatments is unknown because some patients received a series of treatments with an unreported exact number of treatments. In the earliest trial of image-guided CN, one patient experienced a prolonged CSF leak after CN of the inferior sacral nerve roots [22]. This was thought to be caused by an extensive bladder carcinoma that had eroded more than half of the sacrum. In another trial, a patient had vagus-induced syncope, which was easily controlled by the administration of atropine [47].

Another patient had pain in the treated area that was managed by a single steroid injection and later resolved [85]. No other complications that might be considered major per Society of Interventional Radiology guidelines were reported [86]. Pain, swelling, superficial infection, or minor bleeding at the treatment site were most common among the 24 reported minor complications. In summary, approximately 702 procedures resulted in three major and 24 minor complications, with no permanent sequelae reported.

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