

Medical Policy Manual

Topic: Pulsed Radiofrequency for Chronic Spinal Pain

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Section: Surgery

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Percutaneous radiofrequency (RF) denervation is a procedure used to treat certain types of neck or back pain. The goal is long-term pain relief. However, the nerves regenerate, and repeat procedures may be required. RF therapy may be performed using either conventional continuous RF current, which is considered the current standard of care for RF denervation, or pulsed RF current. In conventional continuous RF therapy, probe tip temperatures reach at least 60°C and are intended to produce long-term pain relief through coagulation of tissue. Pulsed radiofrequency (PRF), which consists of short bursts of current, is suggested as a possibly safer alternative to thermal radiofrequency. Temperatures for PRF do not exceed 43°C at the probe tip and do not heat the tissue enough to cause coagulation. In addition, with PRF, tissues may cool between pulses. It is postulated that with PRF denervation transmission across small unmyelinated nerve fibers is disrupted but not permanently damaged, while large myelinated fibers are not affected.

A variety of terms may be used to describe RF denervation (e.g., rhizotomy, rhizolysis, neurolysis, neurotomy, lesioning). In addition, the structures to which the RF energy is directed may be referred to as facet joint, facet nerves, medial nerve or branch, median nerve or branch, segmental nerves, dorsal ramus, or dorsal root ganglion.

MEDICAL POLICY CRITERIA

NOTE: This policy does not address conventional percutaneous radiofrequency facet denervation which may be considered medically necessary for the treatment of facet joint pain that is not responding to conservative treatments. This policy addresses only pulsed radiofrequency procedures that are performed to achieve facet joint denervation; clinical records should clearly document that the pain being treated originates from the facet

joint(s), verified by nerve block, and that the goal of the treatment is facet joint denervation.

Pulsed radiofrequency lesioning of spinal structures (e.g., dorsal root ganglion; medial branch nerve) is considered **investigational** for the treatment of pain from any cause in any level of the spine, including but not limited to the following:

- A. Cervicobrachialgia
- B. Cervicogenic headache
- C. Degenerative conditions such as spondylosis, spondylolisthesis, or degenerative disc disease
- D. Facet joint or zygapophyseal joint arthropathy
- E. Failed back surgery syndrome (FBSS)
- F. Herniated intervertebral disc
- G. Nerve root compression
- H. Neuropathic spinal pain
- I. Radiculopathy, radiculitis, or radicular pain
- J. Scoliosis
- K. Spinal stenosis
- L. Trauma or injury

SCIENTIFIC EVIDENCE

The principal outcome for treatment of pain is symptom relief and improved functional level. Relief of pain is a subjective outcome that is typically associated with a placebo effect. Therefore randomized controlled trials (RCTs) are important to control for the placebo effect and determine its magnitude, and to determine whether any treatment effect provides a significant advantage over the placebo. In addition, trials comparing pulsed radiofrequency (PRF) therapy with conventional continuous radiofrequency (RF) therapy are important to determine the overall effectiveness of this therapy for the treatment of chronic spinal pain.

Literature Appraisal

Systematic Reviews

In a 2008 review of evidence for continuous RF and PRF, Van Boxem and colleagues noted that RF at the cervical and lumbar level has produced the most solid evidence and differences in outcome among RCTs can be attributed to differences in patient selection and/or inappropriate technique.^[1] Studies of cervical radicular pain suggested a comparable efficacy for continuous RF and PRF. There was insufficient evidence to determine the efficacy of facet joint denervation for cervicogenic headache. The superiority of RF treatment adjacent to the lumbar dorsal root ganglion for lumbar radicular pain had not been demonstrated in an RCT. The authors

suggested that future research should be conducted in carefully selected populations and that tests used to select patients for such trials could help physicians select patients for treatment.

In a more recent systematic review Chua et al^[2] found four RCTs that compared PRF of spinal structures with sham intervention^[3] or with conventional continuous RF thermocoagulation^[4-6]. The authors considered the evidence for PRF of the dorsal root ganglion “compelling” for treatment of cervical radicular pain, but found the evidence for PRF for lumbosacral pain to be of low methodological quality. The following is a summary of these RCTs:

- One small RCT comparing pulsed RF to sham treatment was identified in the literature review. Van Zundert and colleagues randomized 23 patients (of 256 screened) with chronic cervical radicular pain.^[3,7] Success was defined as at least 50% improvement on global perceived effect (GPE), at least 20% reduction in pain on visual analog scale (VAS), and reduced pain medication use measured 3 months after treatment. Nine of 11 patients in the treatment arm and 4 of 12 in the sham arm showed at least 50% improvement on GPE ($P=0.03$), and 9 of 11 in the treatment group and 3 of 12 in the sham group achieved at least 20% reduction in pain on VAS ($P=0.02$). At 6 month follow-up, more patients in the treatment group reduced their use of pain medication, but the difference was not significant. There was a trend toward more positive outcomes in the pulsed RF group on quality of life scores. The authors conclude that pulsed RF may provide pain relief for a limited number of carefully selected patients. These findings must be confirmed in larger studies before drawing conclusions regarding the efficacy of pulsed RF.
- Tekin and colleagues randomized sixty patients with lumbar facet joint pain, 20 each to conventional RF, pulsed RF and a control group (local anesthetic only).^[5] Outcome measures were pain on VAS and Oswestry Disability Index (ODI) scores. Mean VAS and ODI scores were lower in both treatment groups than in controls post-treatment; however the reduction in pain was maintained at 6- and 12-month follow-up only in the conventional RF group. The number of patients not using analgesics and patient satisfaction were highest in the conventional RF group.
- A randomized, double blind, prospective trial by Kroll and colleagues compared the efficacy of continuous versus pulsed in the treatment of lumbar facet syndrome in an RCT with 50 patients.^[6] Outcome measures, pain on visual analog scale (VAS) and Oswestry Low Back Pain and Disability Questionnaire (OSW), were administered at baseline and 3 months after treatment and relative percentage improvement compared between groups. No significant differences in the relative percentage improvement were noted between groups in either VAS ($p = 0.46$) or OSW scores ($p = 0.35$). Within the percutaneous RF group, comparisons of the relative change over time for both VAS ($p = 0.21$) and OSW scores ($p = 0.61$) were not significant. However, within the continuous RF group, VAS ($p = 0.02$) and OSW scores ($p = 0.03$) changes were significant. The authors conclude that though there was no significant difference between continuous and pulsed RF in the long-term outcomes, there was greater improvement over time in the continuous RF group.
- Simopoulos et al randomized 76 patients with chronic refractory lumbosacral radicular pain to one of two groups who received either PRF alone or PRF followed immediately by continuous RF.^[4] Two months after the procedure 70% and 82%, respectively, reported successful reduction of pain. These effects were lost by 8 months in most patients. The between-group difference was not significant. The authors concluded that additional randomized controlled trials are required to determine the effectiveness of PRF.

Randomized Controlled Trials

No new randomized controlled trials have been published since those included in the systematic reviews summarized above.

Nonrandomized Trials

The remaining evidence is limited to a small number of nonrandomized case series^[8-11] and retrospective reviews^[12,13] that are difficult to compare due to heterogeneity of participants, definitions of success, and procedure techniques. Evidence from case series, observational studies, and retrospective reviews are considered unreliable due to the following methodological limitations:

- Non-random allocation of treatment which may introduce selection or response bias.
- Lack of appropriate comparison groups, which does not permit conclusions on the efficacy of PRF compared to other treatment options.
- Small study populations which limit the ability to rule out the role of chance as an explanation of findings.
- Variable patient baseline characteristics such as severity of conditions and co-morbidities which may bias treatment effect estimates.

Clinical Practice Guidelines and Position Statements

There are currently no evidence-based clinical practice guidelines that recommend the use of pulsed RF therapy for the treatment of spinal pain.

- American Pain Society (APS)^[14]

In 2009, the APS published an evidence-based clinical practice guideline on nonsurgical interventions for low back pain addressed RF therapy but did not differentiate between continuous and pulsed RF denervation techniques. The guideline states that “there is insufficient (poor) evidence from randomized trials (conflicting trials, sparse and lower quality data, or no randomized trials) to reliably evaluate” a number of interventions including RF facet denervation.

- American Society of Anesthesiologists (ASA)^[15]

The 2010 updated guidelines included recommendations related to conventional RF techniques but did not address pulsed RF.

- American Society of Interventional Pain Physicians (ASIPP)^[16]

The 2013 updated evidence-based guidelines for interventional treatment for chronic back pain rated the evidence on pulsed RF therapy as “limited” based on only 1 RCT currently published. The guidelines include recommendations for conventional RF, but do not include pulsed RF for any indication.

- The American Academy of Orthopaedic Surgeons endorses the 2009 APS guidelines.^[17]

Summary

The current evidence is insufficient to permit conclusions about the long-term benefits and harms of pulsed radiofrequency (PRF) of spinal structures for the treatment of spinal pain. The current evidence is limited to data from small, short-term randomized controlled trials, case series, and retrospective reviews which are considered unreliable due to methodological limitations. There is a lack of long-term data comparing PRF with conventional treatments for spinal pain, so it is not known if PRF offers any treatment advantage over conventional treatments. In addition, there are no clinical practice guidelines from U.S. professional associations that recommend the use of PRF for spinal pain. Therefore, pulsed radiofrequency lesioning of spinal structures at any spinal level is considered investigational for the treatment of pain from any cause.

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CROSS REFERENCES

None

CODES	NUMBER	DESCRIPTION
<p>The June 2005 American Medical Association's CPT Editorial Panel decision that the unlisted CPT code 64999 should be used for pulsed RF treatment remains current. The nerve destruction codes within the 64600-64681 code range are not appropriate for reporting therapies that are not destructive of the target nerve, including but not limited to pulsed radiofrequency.</p>		
CPT	64999	Unlisted procedure, nervous system