Ablative Treatments for Occipital Neuralgia, Chronic Headaches and Atypical Facial Pain *

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DESCRIPTION

Nerves send messages to the brain, including pain signals. When there is an injury or other problem, a message of pain travels along the nerve, to the spinal cord, and then into the brain. One way to treat chronic pain is to destroy, i.e., ablate a small portion of the nerve that is sending the pain signal.

Ablative procedures may be performed in attempt to denervate the occipital nerve (greater or lesser), upper cervical nerve (e.g., second cervical nerve also known as C2), supraorbital, supratrochlear or sphenopalatine ganglion. The proposed goal of denervation is to "shut off" the pain signals that are sent to the brain from the joints and nerves. An additional purported objective is to reduce the likelihood of, or to delay, any recurrence that may occur by selectively destroying pain fibers without causing excessive

sensory loss, motor dysfunction or other complications. Ablative treatments for occipital neuralgia, chronic headaches (including but not limited to cervicogenic headaches, migraines, cluster headaches, tension headaches) and persistent idiopathic facial pain (atypical facial pain) have been proposed for pain relief.

Numerous treatments for headaches (e.g., migraine, cluster headaches, tension type headaches and cervicogenic headache), occipital neuralgia and persistent idiopathic facial pain (PIFP) (atypical facial pain) have been proposed, with varying levels success. The consensus on standard treatment does not exist, because of the variability in patient selection and clinical outcomes. Pharmacological treatment with oral analgesics, anti-inflammatory medications, tricyclic antidepressants, and anticonvulsant medications have been used alone or in combination with other treatment modalities. Other treatment modalities suggested are the use of cervical collar during the acute phase; physical therapy with stretching and strengthening exercises; postural training; relaxation exercises; transcutaneous nerve stimulation (TENS); and manual therapy including spinal manipulation and spinal mobilization. Pharmacological and alternative treatment modalities are not effective for some individuals, and therefore, other treatment methods have been proposed, such as local injections of anesthetics and/or steroids, epidural steroid injections and ablative treatments to include but not limited to pulsed radiofrequency ablation (PRFA); radiofrequency ablation (RFA); cooled radiofrequency; chemical neurolysis (chemical ablation or chemodenervation); and cryoneurolysis (cryoablation, cryotherapy or cryoanalgesia), to attempt to denervate the occipital and/or upper cervical nerve(s) for pain relief.

Headaches

The International Headache Society (IHS) created a headache classification system (The International Classification of Headache Disorders, 3rd edition) which is considered the standard for diagnosis of all types of headaches. The three classifications are: primary headaches; secondary headaches; and painful cranial neuropathies, other facial pains and other headaches. See the descriptions below for these chronic headache types:

- **Chronic Migraine**: Migraine is a common disabling primary headache disorder. Chronic migraine headache is defined as headache occurring on 15 or more days per month for more than three months, which, on at least eight days/month, has the features of a migraine headache.
- **Chronic tension type headache**: A disorder evolving from frequent episodic tension type headache, with daily or very frequent episodes of headache, typically bilateral, pressing to tightening in quality and of mild to moderate intensity, lasting hours, to days or unremitting. The pain does not worsen with routine physical activity, but may be associated with mild nausea, photophobia or phonophobia.
- **Chronic cluster headache**: Chronic cluster headaches is one of the trigeminal autonomic cephalagias (TACs), a group of primary headache disorders characterized by unilateral trigeminal distribution pain that occurs in association with ipsilateral cranial autonomic features. Cluster headache is characterized by attacks of severe unilateral, orbital, supraorbital or temporal

pain. In the episodic form, attacks occur daily, usually one to eight times a day for several weeks, followed by a period of remission. The chronic form of cluster headaches occurs for one year or longer without remission, or with remission periods lasting less than 3 months.

- **Cervicogenic headache**: The clinical features of cervicogenic headache may mimic those associated with primary headache disorders (e.g., tension-type headache, migraine, or hemicranias continua), making it difficult to distinguish among headache types. Cervicogenic headaches is characterized by continuous, unilateral head pain radiating from the occipital areas to the front area, with associated neck pain and ipsilateral shoulder or arm pain. The headache is moderate in intensity with non-throbbing character. It is described as dull, boring, dragging pain that can fluctuate in intensity. The duration of the headache may range from a few hours to several days, and in some cases several weeks. The pain can be exacerbated by neck movements and is usually caused by neck trauma.
    - The anatomic point for cervicogenic headache is the trigeminocervical nucleus in the upper cervical spinal cord, where sensory nerve fibers in the descending tract of the trigeminal nerve are believed to interact with sensory fibers from the upper cervical roots. This functional intersection of upper cervical and trigeminal sensory pathways is through to allow bidirectional transmission of pain signals between the neck and the trigeminal sensory receptor fields of the face and head.
    - Cervicogenic headache is typically caused by a disorder of the cervical spine and its component bony, disc and/or soft tissue elements, usually but not invariably accompanied by neck pain

The first three cervical spine nerves and their rami are the primary peripheral nerve structures that can refer to pain to the head:

- The C1 spinal nerve (suboccipital nerve) supplies the atlanto-occipital joint. Pathology or injury affecting this joint is a potential source for pain that is referred to the occipital region of the head.
- The C2 spinal nerve and its dorsal root ganglion have a close proximity to the lateral capsule of the atlanto-axial (C1-2) zygapophyseal joint and supply the atlanto-axial and C2-3 zygapophyseal joints. Trauma to, or pathologic changes around, these joints can be a source of referred head pain.
- The third occipital nerve (dorsal ramus C3) has a close anatomic proximity to, and supplies, the C2-3 zygapophyseal joint. Pan from the C2-3 zygapophyseal joint is referred to the occipital, frontotemporal and periorbital regions of the head (third occipital headache).

Occipital Neuralgia

Occipital neuralgia can be a cause of a headache in the occipital region which can be intermittent or continuous. The pain of occipital neuralgia has a sudden onset. It is described as severe, stabbing, electric, shock-like, sharp or shooting. It originates in the nuchal region and immediately spreads towards the vertex. The bouts of pain may start

spontaneously or be provoked by a specific maneuver such as brushing the hair, exposure to cold or moving the neck. Other causes can include myofascial tightening, trauma of C2 nerve root (whiplash injury), prior skull or suboccipital surgery, other types of nerve entrapment, idiopathic causes, sustained muscle contraction, and spondylosis of cervical facet joints.

On examination, pressure, palpation, or percussion over the occipital nerve trunks may reveal local tenderness, trigger painful paroxysms (increase of symptoms), or elicit paresthesia along the distribution of the affected nerve. Percussion of the nerve often reproduces the distribution of pain. Also, cervical range of motion may be restricted, and local posterior neck muscle spasms may be found.

Occipital neuralgia is sometimes accompanied by diminished sensation or dysesthesia (abnormal sensation) in the affected area. The remainder of the neurological examination is typically normal. An abnormal neurological examination is an alert for potential alternative or underlying causes of the symptoms.

Diagnostic local anesthetic nerve blocks may be required for a definitive diagnosis to be obtained. The relief of pain after a diagnostic local anesthetic block of the greater and lesser occipital nerves is generally confirmatory of the diagnosis of occipital neuralgia.

Clinical Context and Therapy Purpose
The purpose of ablative treatments in individuals who have occipital neuralgia, chronic headaches (e.g., cervicogenic headache, migraines, cluster headaches, tension headaches) or persistent idiopathic facial pain (PIFP) (atypical facial pain) is to provide a treatment option that is an alternative to or an improvement on existing therapies.

Populations
The relevant population of interest is individuals with occipital neuralgia, chronic headaches (e.g., cervicogenic headache, migraines, cluster headaches, tension headaches) or persistent idiopathic facial pain (PIFP) (atypical facial pain).

Interventions
The ablative therapies being consider are the following:

- Chemical neurolysis (chemodenervation)
- Cooled radiofrequency ablation
- Cyroneurolysis
- Pulsed radiofrequency ablation
- Radiofrequency ablation

Comparators
The following therapy is currently being used to treat occipital neuralgia, chronic headaches (e.g., cervicogenic headache, migraines, cluster headaches, tension headaches) or persistent idiopathic facial pain (PIFP) (atypical facial pain): conservative management.

Outcomes
The most clinically relevant outcome measures for pain treatments are measures of pain severity and functional limitations. Pain is most commonly measured with a VAS or RNS. Quantifiable pre- and posttreatment measures of functional status are also used, such as the 12-Item and 36-Item Short-Form Health Survey. The time for follow-up is within days to determine the procedural success and months to years to evaluate durability

Ablative Treatments

Pulsed Radiofrequency Ablation
Pulsed radiofrequency (PRF) ablation has been proposed as a possibly safer alternative to non-pulsed or continuous radiofrequency ablation (RFA) in the treatment of a variety pain syndromes. Pulsed radiofrequency uses short bursts of radiofrequency current (heat is dissipated during the silent period), rather than the continuous current, which allows the needle to remain relatively cool so that the tissue cools slightly between each burst, reducing the risk of destroying nearby tissue. Pulsed radiofrequency causes the transmission across small unmyelinated nerve fibers to be disrupted, but not permanently damaged. This is because the temperature will not exceed 42 degrees Celsius, versus 80 degrees Celsius reached in non-pulsed or continuous radiofrequency ablation (RFA).

In a prospective study, Vanedleren et. al. (2010) reported on the results of six months of follow-up in which patients presenting with clinical findings suggestive of occipital neuralgia and positive test block of the occipital nerves underwent a pulsed radiofrequency (PRF) procedure of the nerves. Mean score for pain, quality of life, and medication intake were measured at 1, 2 and 6 months after the procedure. Pain was measured by the visual analog and Likert scales, quality of life was measured by a modified brief pain questionnaire, and medication intake was measured by a Medication Quantification Scale. During a 29-month period, 19 patients were included in the study. Mean visual analog scale and median Medication Quantification Scale scores declined by 3.6 units (P = 0.002) and 8 units (P = 0.006), respectively, during 6- months. Approximately 52.6% of patients reported a score of 6 (pain improved substantially) or higher on the Likert scale after 6 months. No complications were reported. This study was limited by design of the study and lack of long- term outcomes. The authors concluded pulsed radiofrequency treatment of the greater and/or lesser occipital nerve is promising treatment of occipital neuralgia. This study warrants further placebo-controlled trials.

In a prospective study, Halim et. al. (2010) reported on 86 patients who had undergone lateral C1-C2 joint pulsed radiofrequency application, for cervicogenic headache in a single pain center. The percentage of patients who had ≥ 50% pain relief at two months, six months, and one year were 50% (43/86), 50% (43/86), and 44.2% (38/86), respectively. Long-term pain relief at 6 months and 1 year were predicted reliably by >or=50% pain relief at 2 months (P < 0.001). One patient complained of increased

severity of occipital headache lasting several hours. This study was limited by design of the study and lack of long-term outcomes.

In a case series report, Zhang, et. al. (2011) reported on pulsed radiofrequency for two patients with cervicogenic headache. After initial positive response to the greater occipital nerve block, pulse radiofrequency (PRF) was performed on the position of the second cervical ganglion (C2). Two patients reported 100% pain relief lasting for 6 months. The lateral puncture is safer and more comfortable than the posterior site. The authors concluded this case study demonstrates effectiveness of PRF to treat cervicogenic headache originating from the C2 nerve. However, we need to further evaluate the results using more samples.

In a retrospective study, Huang et. al. (2012) reported on pulsed radiofrequency (PRF) for occipital neuralgia to determine whether any demographic, clinical or treatment characteristics are associated with success. A total of 102 patients with primary diagnosis of occipital neuralgia were treated with PRF of the greater or and/or lesser occipital nerve. A positive primary outcome was predefined as ≥ 50% pain relief lasting at least 3 months. The secondary outcome measure was procedural satisfaction. A total of 51% of the patients experienced ≥50% pain relief and satisfaction with treatment lasting three months. This study was limited by design and lack of long- term outcomes.

In a systematic review, Grandhi et. al. (2018) investigated the use of radiofrequency ablation (RFA) and pulsed radiofrequency ablation (PRFA) for the management of cervicogenic headache (CHA). A total of 10 studies met inclusion for review. There were 3 randomized controlled trials, three prospective trials, and four retrospective trials that were evaluated for the impact of RFA or PRFA for cervicogenic headache. The criteria for inclusion were based on identification of articles discussion cervicogenic headaches which were previously treatment resistant and occurred without any other pathology of the craniofacial region or inciting event such as trauma. The systematic review indicated that RFA and PRFA provided a very limited benefit in the management of cervicogenic headache. The authors reported that although numerous case reports have demonstrated benefit, presently there are no high-quality randomized controlled trials (RCTs) and/or strong non-RCTs to support the use of RFA and PRFA in the management of cervicogenic headache.

The available evidence from published studies is insufficient to conclude that pulsed radiofrequency ablation is an effective treatment for occipital neuralgia and chronic headaches (including but not limited to cervicogenic headache, migraines, cluster headaches, tension headaches). Further larger well-designed studies with longer periods of follow-up are needed to evaluate the use of pulsed radiofrequency ablation for these conditions and to identify which patients would benefit from this procedure. The evidence is insufficient to determine the effects of this technology on net health outcomes.

Radiofrequency Ablation (RFA)
A variety of terms may be used to describe percutaneous radiofrequency denervation including radiofrequency ablation (RFA), radiofrequency neuroablation, radiofrequency lesioning, radiofrequency neurotomy, radiofrequency rhizotomy and radiofrequency articular rhizolysis.

Radiofrequency ablation (RFA) is performed under local anesthetic with fluoroscopic guidance. RFA is a minimally invasive method that involves the use of heat and coagulation necrosis to destroy tissue. A needle electrode is inserted through the skin and then into the tissue to be ablated. A high frequency electrical current is applied to the target tissue. A small sphere of tissue is coagulated around the needle by the heat generated (80 to 85°C). It is theorized that the thermal lesioning of the nerve destroys peripheral sensory nerve endings, resulting in the alleviation of pain. However, the results are typically not permanent as the nerves may regenerate which can cause the pain to return and may require the repetition of the RFA procedure to alleviate the pain. Radiofrequency ablation (RFA) has been proposed for the treatment of pain associated with occipital neuralgia and chronic headaches (including but not limited to cervicogenic headache, migraines, cluster headaches, tension headaches) for pain relief.

Stovner et. al. reported on a randomized double- blind sham-controlled study for radiofrequency denervation of facet joints C2-C6 in cervicogenic headache. Twelve patients with disabling, long standing and treatment resistant unilateral cervicogenic headache were included. Six were randomized to receive radiofrequency neurotomy of facet joints C2-C6 ipsilateral to the pain, and six were randomized to sham treatment. Patients were followed for 2 years with diary registration of pain for 14-days periods after 1, 3, 6, 12, 18 and 24 months, and followed with algometry and neck mobility measurements at 3, 12 and 24 months. Side-effects were minor and short-lasting, and those patients who were treated with neurotomy were somewhat improved at 3 months, but later there were no marked differences between the groups. In conclusion, the procedure is probably not beneficial in cervicogenic headache.

Hamer et. al. (2014) reported on a single center retrospective observational study of 40 patients with refractory cervicogenic headaches or occipital neuralgia following treatment with radiofrequency ablation of the C2 dorsal root ganglion and/or third occipital nerves. Patients were all referred by a headache specialty clinic for evaluation for radiofrequency ablation of the C2 dorsal root ganglion and/or third occipital nerves. After treatment, patients were followed for a minimum of 6 months to a year. Patient demographics and results of radiofrequency ablation were recorded on the same day, after 3-4 days and at 6 months to 1 year following treatment. Thirty-five percent of patients reported 100% pain relief and 70% reported 80% or greater pain relief. The mean duration of improvement was 22.35 weeks. Complication rate was 12-13%. This study was limited by design and lack of long- term outcomes.

Nagar et. al. (2015) reported on systematic review of radiofrequency (RF) ablation and pulsed radiofrequency (PRF) for management of cervicogenic headache (CHA). The

primary outcome measures were reduction in pain scores and improvement in quality of life. Twenty- five studies were identified for full text review of these, 9 studies met inclusion criteria. There were 5 non-randomized, among them 4/5 were of moderate quality, 3/5 showed RF ablation and 1/5 showed PRF as an effective intervention for cervicogenic headache. There were 4 randomized trials among them 2/4 were of high quality, 3/4 investigated RF ablation as an intervention for CHA, 1/4 investigated PRF ablation as an intervention for CHA and none of the randomized studies showed strong evidence for RF and PRF ablation as an effective intervention for CHA. In the selected studies there were inconsistencies between randomized trials, flaws in trial design, and gaps in the chain of evidence. The authors concluded, there is limited evidence to support RF ablation for management of CHA as there are no high quality randomized controlled trials (RCTs) and/or multiple consistent non-RCTs without methodological flaws. There is poor evidence to support PRF for CHA as there are no high quality RCTs or Non-RCTs.

In 2016, Hamer et. al. reported on a single center retrospective observational study of 23 patients with recurrent cervicogenic headaches and/or occipital neuralgia treated with repeated radiofrequency ablation (RFA) of the C2 dorsal root ganglion and/or third occipital nerves. All patients receiving treatment from January 2010 to July 2014 were included. This was an IRB approved medical chart review study. Twenty-two of 23 patients underwent follow-up. An average of 86.5% of participants reported pain relief on average of 25.4 weeks at time of follow-up. Forty-one percent reported side effects including suboccipital hyperesthesia and/or ear discomfort, 95% reported a willingness to repeat the procedure again if severe symptoms occurred, 59% of patients reported the most recent RF ablation had the same results as the first, 32% reported the most recent RFA was the most effective and 9% reported that the first RFA was the most effective. The authors concluded repeated RFA is feasible option for recurrent cervicogenic headaches and/or occipital neuralgia. Effectiveness is the same or better than the first ablation, and high likelihood of side effects include suboccipital neuralgia and/or ear discomfort, although side effects were generally well tolerated. Further research is needed to determine if there is a long-term sequela of numerous radiofrequency ablations (RFA), particularly if patients undergo 3 or more ablations. A prospective study with control group would be helpful.

The available evidence from published studies is insufficient to conclude that radiofrequency ablation (RFA) is an effective treatment for occipital neuralgia and chronic headaches (including but not limited to cervicogenic headache, migraines, cluster headaches, tension headaches). Additional randomized controlled clinical trials (RCTs) with longer follow up and larger patient populations are needed. The evidence is insufficient to determine the effects of this technology on net health outcomes.

Cooled Radiofrequency Ablation

Cooled Radiofrequency ablation is a newer alternative to continuous radiofrequency ablation (RFA) and pulsed radiofrequency ablation (PRFA). With cooled radiofrequency ablation a special device is used that utilizes a water- cooled radiofrequency probe to

ablate the lesion (nerve). Cooled radiofrequency ablation applies more energy at the desired location without excessive heat diffusing beyond the area, causing less tissue injury away from the nerve. The goal for ablating the nerve is the same as RFA and PRFA.

In 2014, Vu et. al. reported on a case report of a 35-year-old female with bilateral greater occipital neuralgia treated with cooled radiofrequency ablation. This patient had trialed numerous other treatment options including several nerve blocks, physical therapy, adjuvant pain and nerve medications, and pulsed and continuous radiofrequency ablation. The patient could not tolerate continuous radiofrequency ablation and it was found to be minimally effective. Cooled RFA was provided as an alternative that provided 75% relief in a very difficult to treat case of greater occipital neuralgia. However, the authors noted that the usage of cooled RFA in greater occipital neuralgia has not been documented in the literature and the full effects of this treatment related to this case cannot be determined without follow-up 3, 6 and 12 months.

The available evidence from published studies includes a case report for the treatment of occipital neuralgia, no studies were found using cooled radiofrequency ablation (RFA) in the treatment of chronic headaches (including but not limited to cervicogenic headache, migraines, cluster headaches, tension headaches). Additional randomized controlled clinical trials (RCTs) with longer follow up and larger patient populations are needed. The evidence is insufficient to determine the effects of this technology on net health outcomes.

Cryoneurolysis

Cryoneurolysis, also called cryoablation, cryotherapy or cryoanalgesia uses freezing temperatures to treat chronic pain of either sensory or motor nerves and uses a wide range of temperatures with treatment often occurring at temperature as cold as -196°C (liquid nitrogen coolant) or -20 to -140°C or colder (nitrous oxide coolant). Because peripheral nerve function is disrupted due to the destruction of the axon and myelin sheath, the desired result provides pain relief until the nerve(s) regenerate. Cryodenervation has been used for patients with various types of pain.

In 2015, Chong et. al. reported on a retrospective evaluation on the efficacy and safety of cryoablation for the treatment of occipital neuralgia (ON) in an academic university-based pain management center. All patients received local anesthetic injections of ON. Patients with greater than or equal to 50% relief and less than 2- week duration of relief were treated with cryoablation. Thirty- eight patients were included. Of the 38 patients 20 were treated for unilateral greater occipital neuralgia (ON), 10 for unilateral greater and lesser ON, and 8 for bilateral greater ON. There were 10 men and 28 women, with an average age of 45.2 years and 51.1 years respectively. The average relief for all local anesthetic injections was 71.2%, 58.3% for patients who reported 50-74% relief (Group 1) and 82.75% for patients who reported greater than 75% relief (Group 2). The average improvement of pain relief with cryoablation was 57.9% with an average duration of 6.1 months overall. Group 1 reported an average of 45.2% relief for an average of 4.1 months

with cryoablation. In comparison, Group 2 reported an average of 70.5% relief for 8.1 months. The percentage of relief (P=0.007) and duration of relief (P=0.0006) was significantly improved in those reporting at least 75% relief of pain with local anesthetic injections (Group 2 vs Group 1). Though no significance in improvement from cryoablation was found in men, significance was seen in women with at least 75% benefit with local anesthetic injections in terms of duration (P=0.03) and percentage (P=0.001) of pain relief with cryoablation. The average pain score prior to cryoablation was 8 (0-10 visual analog scale, VAS), this improved to 4.2, improvement of 3.8 following cryoablation at 6 months (P=0.03). Of the 38 patients, 3 (7.8%) adverse effects were seen. Two patients reported post procedure neuritis and one was monitored for procedure related hematoma. Study limitations included the retrospective nature of the study. Additionally, only the percentage relief, pain score and duration of relief were collected. This study was limited by design and lack of long- term outcomes.

Based on review of the peer reviewed medical literature, the literature is limited to a retrospective study. No randomized controlled trials were found. The evidence is insufficient to establish the safety and efficacy of this ablative technique in the treatment of pain associated with occipital neuralgia and/or chronic headaches (including but not limited to cervicogenic headache, migraines, cluster headaches, tension headaches). Further larger well-designed studies with longer periods of follow-up are needed to evaluate the use of cryoneurolysis (cryoablation, cryotherapy or cryoanalgesia) for these conditions and to identify which patients would benefit from this procedure. The evidence is insufficient to determine the effects of this technology on net health outcomes.

Chemical Neurolysis (Chemodenervation)
Chemical neurolysis is also referred to as chemical ablation or chemodenervation, involves an injection of neurolytic agent(s) such as phenol, alcohol, glycerol, or hypertonic saline to cause destruction of nerve(s) by causing a temporary degeneration of the nerve(s) fibers to interrupt the transmission of nerve(s) signals for pain relief. These agents are typically used for nerve blocks but may also be used as local neurolytic injection. However, there is lack of published data to support the safety and efficacy of this technique in the treatment of pain associated with occipital neuralgia and chronic headaches (including but not limited to cervicogenic headache, migraines, cluster headaches, tension headaches). Well-designed randomized controlled trials are needed to establish the safety and effectiveness of this treatment modality for these indications. The evidence is insufficient to determine the effects of this technology on net health outcomes.

Persistent Idiopathic Facial Pain (PIFP) (Atypical Facial Pain)
Persistent idiopathic facial pain (also known as atypical facial pain) is characterized by persistent facial pain that does not have the characteristics of cranial neuralgias and cannot be attributed to a different disorder. The pain is usually of long duration, lasting most of the day (if not continuous), is generally limited to one particular area on one side of the face at onset, is deep and poorly localized, and is not associated with sensory loss

or other neurologic deficits. Investigations including x-ray of the face and jaw or cranial computed tomography (CT) or magnetic resonance imaging (MRI) do not demonstrate any relevant abnormality. The pain may be initiated by surgery or injury to the face, teeth, or gums, but it persists without any demonstrable cause. Persistent idiopathic facial pain (atypical facial pain) is rare, and studies are scarce.

The pathophysiology of persistent idiopathic facial pain (PIFP) (atypical facial pain) is unknown. The available literature suggests that abnormal sensitization of the trigeminal nociceptive system may play a crucial role in the development of PIFP.

Medical treatment of persistent idiopathic facial pain (atypical facial pain), include anticonvulsants and antidepressants (e.g., tricyclic antidepressants, selective serotonin uptake inhibitors and norepinephrine reuptake inhibitors) are the preferred treatment. Ablative treatments have been proposed for the treatment of persistent idiopathic facial pain (PIFP) (atypical facial pain) for pain relief.

The literature on ablative treatments for persistent idiopathic facial pain (atypical facial pain) is limited.

Orhurhu et. al. (2020) completed a systematic review to summarize available evidence behind radiofrequency ablation (RFA) for facial pain, including pain outcome measures, secondary outcomes, and complications. For this systematic review the following were included: randomized controlled trials (RCTs), open nonrandomized control studies, prospective studies, retrospective studied, case series and case reports. The literature search was limited to the following: application of either continuous radiofrequency (CRF) or pulsed radiofrequency (PRF) treatment in adult patients with chronic facial pain lasting for at least 1 month or in patients with a diagnosis of facial pain. Short-term pain relief displayed promising results but did not necessarily correlate with good long-term outcomes.

In 2017, Weiss et. al. reported on comprehensive evidence- based review on atypical facial pain. PIFP is an excruciating disorder of the face often misdiagnosed as trigeminal neuralgia (TN) However, unlike TN symptoms, the pain is persistent rather than intermittent, usually unilateral, and without autonomic signs or symptoms. When a clinician encounters a patient with neuropathic facial pain whose symptoms are incongruent with the more common etiologies, the diagnosis of atypical facial pain must be entertained. The purpose of the article was to focus on atypical facial pain or persistent idiopathic facial pain (PIFP). It is considered an underdiagnosed condition with limited treatment options. New interventional modalities such as pulsed radiofrequency ablation (PFRA) of the sphenopalatine ganglion, peripheral nerve field stimulators (PNFS), and botulinum toxin injections have promising results. In summary, more prospective studies such as randomized controlled trials are necessary to explore the possibility of their more widespread use as viable procedures for the treatment of PIFP. Unfortunately, few randomized controlled trials for the treatment of PIFP exist. However, there are a select

number of pharmacological, non-pharmacological, and interventional treatment options that have proven to be moderately effective.

In 2017, Benoliel et. al. reported on persistent idiopathic facial pain (PIFP) in which the authors concluded the underlying pathophysiology in PIFP is still enigmatic, however neuropathic mechanisms may be relevant. PIFP needs interdisciplinary collaboration to rule out and manage secondary causes, psychiatric comorbidities and other facial pain syndromes, particularly trigeminal neuralgia. Burden of disease and psychiatric comorbidity screening is recommended at an early stage of disease and should be addressed in the management plan. Future research is needed to establish clear diagnostic criteria and treatment strategies based on clinical findings and individual pathophysiology.

The available evidence is insufficient to conclude that ablative treatments including but not limited to radiofrequency ablation, pulsed radiofrequency ablation, cooled radiofrequency, cryoneurolysis (cryoablation, cryotherapy or cryoanalgesia) or chemical neurolysis (chemical ablation or chemodenervation) are effective treatments for persistent idiopathic facial pain (PIFP) (atypical facial pain). While some evidence may show promise regarding short-term pain, results have not correlated with good long-term outcomes. Additional well-designed randomized controlled trials (RCTs) are needed to establish the safety and efficacy of ablative treatments for the treatment of PIFP (atypical facial pain). The evidence is insufficient to determine the effects of the technology on net health outcomes.

Summary of Evidence

The evidence in the peer reviewed published literature evaluating nerve destruction using pulsed radiofrequency ablation (PRFA); radiofrequency ablation (RFA); cooled radiofrequency ablation, cryoneurolysis (also called cryoablation, cryotherapy or cryoanalgesia); and chemical neurolysis (chemodenervation) for the treatment of occipital neuralgia, chronic headaches (including but not limited to cervicogenic headache, migraines, cluster headaches, tension headaches) and persistent idiopathic facial pain (PIFP) (atypical facial pain) is primarily from case reports, prospective and retrospective studies, systematic reviews and few randomized controlled clinical trials (RCTs). Some of the studies yielded promising results showing improvement in pain and decrease in pain medication usage, however, conclusive evidence demonstrated in well-designed clinical studies in support of these ablative treatments is warranted. While these treatment modalities appear to be safe, the evidence of efficacy is limited. Further placebo-controlled trials are needed. The overall quality of evidence is low. Studies were limited by methodological flaws, such as small sample size, lack of a control group, and short follow-up. Before definitive conclusions can be drawn, there is a need for high quality studies with larger populations, adequate follow-up time, standardized treatment protocols, and comparisons of the treatment being studied with other treatments used for the same diagnosis which has failed conventional treatments. The evidence is insufficient to determine the effects of this technology on net health outcomes.

Practice Guidelines and Position Statements

American Society of Anesthesiologists Task Force and American Society of Regional Anesthesia and Pain Medicine
In 2010, the American Society of Anesthesiologists Task Force and American Society of Regional Anesthesia and Pain Medicine issued a practice guideline for chronic pain management which included the following:

Ablative techniques include chemical denervation, cryoneurolysis or cryoablation, thermal intradiscal procedures (i.e., intervertebral disc annuloplasty (IDET), transdiscal bioaculopathy), and radiofrequency ablation.

Recommendations for Ablative Techniques:

- Chemical denervation: (e.g., alcohol, phenol, or high concentration local anesthetic) should not be used in the routine care of patients with chronic non-cancer pain.
- Cryoablation: may be used in the care of selected patients (e.g., post-thoracotomy pain syndrome, low back pain (medial branch), and peripheral nerve pain)

The American Association of Neurological Surgeons (AANS)
The American Association of Neurological Surgeons (AANS) patient website on occipital neuralgia states: "The goal of treatment is to alleviate pain. Often symptoms will improve or disappear with heat, rest, and/or physical therapy, including message, anti-inflammatory medications, and muscle relaxants. Oral anticonvulsant medications such as carbamazepine and gabapentin also may help alleviate pain. Percutaneous nerve blocks not only may be helpful in diagnosing occipital neuralgia, but they can help alleviate pain. Nerve blocks involved either the occipital nerves or in some patients the C2 and/or C3 ganglion nerves. Surgical interventions (i.e., microvascular decompression) may be considered when the pain is chronic and severe and does not respond to conservative treatment." This information does not mention ablative treatments. (*Accessed July 2022*)

Regulatory Status
Radiofrequency ablation (RFA) is a procedure and, therefore, is not subject to regulation by the FDA. However, the devices used to perform RFA are regulated by the FDA premarket approval process. There are numerous devices listed in the FDA 510(k) premarket approval process.

PRIOR APPROVAL

Prior approval is required

POLICY

See Related Medical Policies

- 07.01.73 Ablative Procedures of the Peripheral Nerves to Treat Pain*

- 02.01.52 Injection Therapy for Headache Management
- 07.01.51 Occipital Nerve Stimulation
- 07.01.41 Pulsed Radiofrequency Ablation
- 07.01.58 Radiofrequency Ablation and Alternative Ablative/Denervation Methods for Chronic Facet Joint Mediated Neck, Back and Sacroiliac Joint Pain*

Ablative treatments including but not limited to the following, for the treatment of occipital neuralgia and/or chronic headaches (e.g., cervicogenic headache, migraines, cluster headaches, tension headaches) or persistent idiopathic facial pain (PIFP) (atypical facial pain) is considered **investigational**:

- Radiofrequency ablation (RFA) (also known as radiofrequency denervation; radiofrequency neurotomy; radiofrequency rhizotomy)
- Pulsed radiofrequency ablation *(Refer to medical policy 07.01.41 Pulsed Radiofrequency Ablation)*
- Cooled radiofrequency ablation
- Cryoneurolysis (cryoablation, cryotherapy, cryoanalgesia)
- Chemical neurolysis (chemical ablation or chemodenervation)

The evidence in the peer reviewed published literature evaluating the above ablative treatment methods is primarily from case reports, prospective and retrospective studies, systematic reviews, and few randomized controlled clinical trials (RCTs). Some of the studies yielded promising results showing improvement in pain and decrease in pain medication usage, however, conclusive evidence demonstrated in well-designed clinical studies in support of these ablative treatments is warranted. While these treatment modalities appear to be safe, the evidence of efficacy is limited. Further placebo-controlled trials are needed. The overall quality of evidence is low. Studies were limited by methodological flaws, such as small sample size, lack of a control group, and short follow-up. Before definitive conclusions can be drawn, there is a need for high quality studies with larger populations, adequate follow-up time, standardized treatment protocols, and comparisons of the treatment being studied with other treatments used for the same diagnosis which has failed conventional treatments. The evidence is insufficient to determine the effects of this technology on net health outcomes.

PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- 64600 Destruction by neurolytic agent, trigeminal nerve; supraorbital, infraorbital, mental, or inferior alveolar branch
- 64633 Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint
- 64640 Destruction by neurolytic agent other peripheral nerve or branch

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POLICY HISTORY

Date	Reason	Action
July 2022	Annual Review	Policy Renewed

March 2022	Interim Review	Policy Revised
July 2021	Annual Review	Policy Renewed
July 2020	Annual Review	Policy Renewed
July 2019	Annual Review	Policy Revised
August 2018	Annual Review	Policy Revised
August 2017	Annual Review	Policy Revised
October 2016	Annual Review	Policy Revised
October 2015	Annual Review	Policy Revised
November 2014		New Policy

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

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