Cryoablative Procedure For Back Pain

Orlando G. Florete Jr., M.D. Orlando G. Florete, Jr. M.D. is Co-Director of the Baptist Institute of Pain Management.

Introduction

The use of cryoanalgesia in the management of chronic pain syndrome is gaining acceptance. It is particularly useful when other modalities of pain relief are unacceptable to patients such as surgery or device implantation, too difficult to perform, have a high incidence of complications or side effects, or has been ineffective. The techniques has been utilized in the treatment of various types of neuralgias (fascial, intercostal, postherpetic, posttraumatic), myofascial trigger point pain, post-surgical pain, cancer pain, neuroma, phantom limb pain, cervicogenic headache, cervicalgia, thoracic, lumbar and coccygeal pain. It is an outpatient procedure, readily acceptable to patients, minimal complications, and an effective alternative to pharmacologic pain killers.

Historical Perspective

The analgesic effect of cold was first recorded by Hippocrates.¹ Early physicians such as Avicenna used cold for preoperative analgesia. Robert Boyle published a classic monograph nearly three hundred years ago entitled "New Experiments and Observations Touching Cold". In 1851, Arnott reported the application of cold in relieving cancer pain.² Smith and Fay in 1939 reported finding regression of tumor following localized freezing.³ The first cryoprobe was developed by Cooper and colleagues in 1961.⁴ Subsequently, Amoils developed a more practical enclosed gas expansion cryoprobe that operated based on the Joule-Thompson principle.⁵ In the early 1970's, the concept of therapeutic peripheral nerve freezing was reintroduced by Nelson, Brain, Lloyd and others.⁶⁻⁸ Lloyd and coworkers in 1976 used this method for pain relief and coined the term "cryoanalgesia".⁸

Mechanism of Analgesia

The basic mechanism by which pain relief results from application of freezing is the development of intracellular and extracellular ice crystals.⁹ This creates a series of biochemical, anatomic and physiologic events in nerve tissues causing increased tonicity of intracellular and extracellular fluids, damage to cellular proteins, cell membrane disruption caused by rapid water loss, and physical destruction of the myelin sheath and Schwann cells. Additionally, there is an associated vascular damage, allowing plasma and extracellular fluid extravasation into the endoneurium. Elevation of endoneural fluid pressure is highly associated with the development of Wallerian degeneration, whereby the axon and the myelin sheath degenerate from the point of freezing distally to the nerve termination.

The size and length of nerve destruction is temperature dependent. The intensity and duration of analgesia is dependent on the degree of nerve damage. Nerve damage can be categorized as:

- a. **First degree or Neuropraxia:** produces minimal damage and disrupts neural function for approximately two weeks.
- Second degree or Axonotmesis: destruction of the axon and b. myelin sheath, with pain relief for several months. This is the degree of nerve injury sought by nerve cryolesioning and is achieved by application of temperature at least -20 degrees centigrade. This results in axonal damage at the site of injury but the fibrous architecture of the nerve including the endoneurium, perineurium and epineurium is preserved. Nerve regeneration occurs almost immediately at a rate of 1-1.5 mm a day and regeneration within the intact endoneural tube occurs from the point of injury distally. Nerve histology remains normal but slower nerve conduction velocity persists up to 35 days after the new myelin sheath are fully formed.¹⁰ The rate and extent of cryolesioning is dependent on the proximity of the nerve to the cryoprobe, size of the cryoprobe, temperature attained by the tissue in proximity to the cryoprobe, and the rate of freezing and defrosting. The closer the probe to the nerve, the greater and more intense the neurolysis. Cryoprobes are available in various

sizes. The standard freeze zones that could be created at equilibrium were 10 and 6 mm with the 14 and 16 gauge gas expansion cryoprobe, respectively.¹¹ Repeated freeze-thaw cycle significantly increases the size of the lesion.¹² Repeated cycles decrease the temperature at more distal sites from the cryoprobe and increases the freeze zone by as much as 70 percent.

c. Third to Fifth degree or Neurotmesis: destruction of both neural and stromal tissues with longer duration of analgesia. Regeneration and return of function is unpredictable. The fibrous architecture is destroyed such that neuroma formation and neuritis can develop. The subsequent pain associated with this complication may be more intense than the original pain. Incomplete and abnormal nerve regeneration may manifest itself as "anesthesia dolorosa". Fifth degree injury is irreversible and no nerve regeneration occur, although neuroma can still form. Equipment

Spembly Cryosurgical System

- a. *Nitrous oxide delivery system* allows safe delivery of nitrous oxide of up to 850 psi to the gas expansion orifice in the tip of the cryoprobe. The machine is provided with a gas pressure regulator switch and dials to record gas pressure. Nitrous oxide is the refrigerant and is provided in an E cylinder tank. Modification of the gas attachment to the unit allows us to use of the bigger G gas tanks. Generally, the gas is delivered at an operating pressure of 600 psi. The minimum temperature at the tip of the probe can rapidly reach to -60 degrees centigrade.
- b. *Temperature measuring facility* contains a dial to measure the cryoprobe tip temperature.
- c. Battery operated nerve stimulator Cryoprobe

A cryopobe is a polytetrapolyethylene coated gas expansion probe of various gauges (14, 16, 18 gauge). It contains the freezing probe and the electronic stimulator. It has 6 feet of flexible connecting cable that is attached to the console unit of the cryomachine.

Indications For Cryoanalgesia

- 1. Chronic Pain Syndromes including
- a. Chest wall pain
- b. Facial pain syndromes such as tic douloureux and other nonherpetic neuralgias
- c. Occipital, suprascapular, ilio-inguinal and other specific neuralgias
- d. Facet syndrome including cervical, thoracic and lumbosacral
- e. Coccydynia
- f.Perineal neuropathies
- g. Phantom Limb
- h. Trigger points
- i. Painful neuromas
- j. Painful superficial scars
- k. Chronic low back pain with radiculopathy

2. Acute postoperative pain from thoracotomy and inguinal hernia repair

3. Cancer pain

Effectiveness Of Cryoablation

The therapeutic effectiveness of cryoablation is difficult to predict. There is wide patient to patient variability depending upon the site of lesioning, nature of the pain problem, psychologic make up of the individual, and experience of the operator. Across the board, the effectiveness may vary from 3 to 1000 days.

Complications

- 1. Frostbite to the skin with full thickness damage most common, may result in depigmentation
- 2. Pneumothorax
- 3. Damage to adjacent structures may occur if there is leakage of refrigerant and the cryoprobe shaft is frozen.

4. Motor damage - usually reversible Specific Cryolesioning For Back Pain

Spinal Pain - Cervical, Thoracic And Lumbo-sacral

The causes of spinal/back pain is complex. Seventy to eighty percent of an adult working population experience spinal pain in some stage of their life.¹³ Only 15% of patients with low back pain have been identified to have specific etiology such as disc protrusion, infection, spondylolisthesis or a vertebral fracture.¹⁴ In most cases, the mechanism remains unclear in spite of extensive diagnostic work up. Radiographic abnormalities are often non-specific and do not correlate with the patient's clinical presentation.¹⁵ The pain resolves within a few weeks in majority of these patients and 80 percent return to function in about two months. Five to twelve percent of this population have complaints lasting for a longer period. In those patients where the pain persists for more than 6 months, spontaneous relief is not to be expected.

One of the unrecognized causes of failure to relieve back pain after repeated laminectomies and spinal fusion is an underlying facet arthropathy. The zygapophyseal process has been implicated as a possible site of intractable low back pain syndromes and sciatica.¹⁶ A prerequisite to cryoablation is the performance of diagnostic facet block using a local anesthetic with or without steroid at least two times under fluoroscopic guidance. False positive responses to a single prognostic block are found in 27-50 percent of patients, thus at least two blocks are required prior to cryoablation.^{17,18} If the patient obtained pain relief more than the expected pharmacologic duration of the drug, then the patient is considered for cryoablation. If the patient is non-responsive to the diagnostic block, cryoablation is generally unsuccessful.

A successful facet cryoablation depends upon the extent of neurolysis of the facet nerve (Nerve of Luschka). The neural supply of the spine is complex. The sinuvertebral nerve innervates the anterior aspect of the dura, the posterior longitudinal ligament, and the dorsal aspect of the annulus fibrosus at the cervical level. Each nerve arises from a somatic and autonomic root. The somatic root originates from the ventral ramus at each segmental level, while the autonomic roots are derived from the vertebral nerve. The postero-lateral and lateral aspects of the cervical discs are supplied by the vertebral nerve. The posterior portion of the spine is supplied by the posterior primary rami of the segmental nerve. The segmental nerve curves posteriorly in a groove formed by the superior articular and transverse processes, dividing into a medial and lateral branch. The facet joints are innervated by the medial branch of the dorsal ramus, communicating with other medial branches above and below it such that each joint is served by multiple segments.

At the lumbar level, the posterior aspect of the spine is innervated by the posterior primary ramus of the segmental nerve. The segmental nerve also divides in a medial and lateral branch. The medial branch innervates the facet joints in such a way that each joint is served by at least three segmental levels. The anterior aspect of the dura and the posterior longitudinal ligament are innervated by the sinuvertebral nerve. The posterolateral parts of the annulus fibrosus are innervated by small branches of the anterior primary ramus. The anterior and antero-lateral part are innervated by rami of the grey ramus communicans.

Pain in the Cervical Area

Cervical pain syndromes can be divided into three clinical types:

- 1. **Cervical pain:** pain originating from the facet joints or from the disc. No clinical criteria has been established to make a diagnosis of cervical facet joint pain. Diagnostic facet injection can help establish the diagnosis. Midline cervical pain may point to a nociceptive focus at the disc. Cervical discogram, either provoked or nerve block confirms the diagnosis.
- 2. **Cervicogenic headache:** unilateral headache originating from the cervical spine precipitated by movements of the neck or local pressure on tender spots in the cervical area. Segmental block at C2, C3, C4 and C5 levels in the symptomatic side transiently

relieves the pain.

3. **Cervicobrachial pain:** pain originating from the cervical spine, with referral to a particular spinal segment. It is localized in the mid and lower cervical area with radiation into the shoulder and/or arm. The pain generator may be located in the dural sheath of the nerve root, the facet joints, or the nerve fibers in the outer annulus. Nerve root pain may be caused by a herniated disc or be degenerative narrowing of the intervertebral foramen. The patient may complain of localized paravertebral tenderness in the spine.

Thoracic Pain

Thoracic pain is the least common spinal pain, accounting for 5-10 percent of patients. Non-spinal etiology should be ruled such as aneurysms, tumors, old fractures, cardiovascular abnormalities, or infection. Two clinical types of thoracic pain are identified:

- 1. **Mechanical thoracic pain:** originates from the facet joint and/or thoracic disc. No clinical criteria has been established to diagnose thoracic pain due to facet arthropathy. It is usually associated with a degenerative process, vertebral collapse or postural abnormalities. The patient may have unilateral or bilateral pain in a localized area of the thoracic spine and there may be paravertebral tenderness on palpation over the facet joints. A diagnostic facet block may help confirm the diagnosis. Thoracic discogram can be performed to identify a pain generator originating from a disc but no formal publication has been described due to increased risk of pneumothorax.¹⁹
- 2. **Thoracic segmental pain**: thoracic pain with segmental radiation due to involvement of the segmental nerve in the pain syndrome. Clinical diagnosis is unclear and made by exclusion. A diagnostic segmental nerve block may help establish the diagnosis.

Lumbar Pain

Lumbar pain is the most common type of spinal pain, and can be categorized into two general types:

- 1. **Mechanical low back pain:** pain originating either from the facet joint or the disc. Facet pain may be referred to the buttock and to the thigh. There is often pain on hyperextension and the pain may be provoked by sudden movement. Paravertebral tenderness is a common finding. A diagnostic facet block confirms the diagnosis. Discogenic pain is due to disruption of the disc and the leakage of the nucleus pulposus material into the annulus fibrosus. Degeneration of the disc may also be a source of pain. A midline tenderness is usually elicited on palpation and an increase in pain is noted on flexion rather than back extension.
- 2. **Nerve root pain:** characterized by dermatomal radiation usually well into the leg and often into the foot. There may be variable loss of nerve function and signs of sympathetic hyperactivity.

Cryoablative Technique

Cervical Cryoablation

For cervical cryoablation, at least three levels are performed. The suspected facet pain generators are identified under fluoroscopic guidance. The head is turned to the contralateral side to have a better view of the planned cryoablated side. The patient may be given an anxiolytic agent but sedation should be avoided. The patient should be awake during pain replication to insure success of the procedure. Non-invasive monitors including a blood pressure cuff, pulse oximeter and an EKG are put in place and vital signs are monitored every five minutes during the entire procedure. The neck and back area are aseptically prepped and draped.

The skin and the underlying soft tissues are locally infiltrated with 1 percent lidocaine. A scalpel Number 11 blade is used to make a small skin incision. A gauge 12 angiocatheter needle is inserted through the skin insertion and directed towards the facet area under fluoroscopic guidance. Once the needle comes in contact with the bone, the stylet is removed. The cryoprobe is inserted into the outer cannula. I prefer to use the 14 gauge cryoprobe. The area is then mapped for localization of the pain generator using the built in nerve stimulator. The

stimulator delivers direct electrical current that has continuous pulses of 1 msec. The patient pain is replicated at a minimum stimulation of 1 volt or less when the cryoprobe lies in close proximity to the facet nerve. If the patient complains of radicular pain and muscle contractions are noted at 1-2 volts, the cryoprobe is in close proximity with the spinal nerve. The cryoprobe is repositioned until replication of the original pain at minimal stimulation occurs without motor involvement. Placement of the probe is confirmed by fluoroscopy and the cryoprobe is activated for 2 minutes at a maximum temperature of -72 degrees centigrade. This is followed by defrosting for at least 10 seconds. The cycle is repeated one more time. At the end of the second freeze-thaw cycle, the cryoprobe is removed and 2 cc of 0.5 bupivacaine is injected into the outer cannula before the cannula is removed.

The procedure is repeated at an additional two or more levels depending upon the patient's tolerance to pain. Usually, I do cryoablation one side at a time. The puncture site may be covered with bandage. The patient is then brought to the PACU for at least 30 minutes before discharge to a responsible individual. The patient is given a prescription of an oral analgesic for postprocedural pain. Patients may complain of pain and discomfort for as long as 10-14 days. If indicated, the patient is asked to come three weeks later to have the opposite side cryoablated.

Thoracic Cryoablation

For thoracic cryoablation, the patient is placed in a prone position. Similar preparations are made as described above. The major difference is in the duration and number of the freeze thaw cycle. I prefer to use three minutes of freezing followed by 10 seconds of defrosting. The procedure is done three times instead of two. The rest of the procedure is similar.

Lumbar Cryoablation

For lumbar cryoablation, the patient is placed in prone position with a pillow placed under the iliac crest. The procedure done is similar to

that performed during thoracic cryoablation.

In some patients, the presence of sacroilitis may contribute to the back pain. Tenderness on palpation of the sacroiliac joint, a positive Patricks test (leg cross over) and radiographic evidence of sacroiliac degeneration indicate that this joint may have major pain generators. This area can be cryoablated in a similar fashion as in lumbar cryoablation.

Coccydynia

Pain in the coccygeal area due to a variety of causes. The coccygeal nerve is cryoablated by inserting the cryoprobe through the sacrococcygeal membrane intro the sacral epidural space at the level of the sacral cornu. Similar positioning, monitoring and preparation are done as in lumbar cryoablation. A smaller cryoprobe is utilized (gauge 18) because of the technical difficulty of inserting a gauge 14 through the sacral hiatus. The cryoprobe is first directed on one side with the tip lying in line with the sacral cornu. Nerve stimulation is done to replicate the pain and exclude motor involvement. Once replicated, 2 two-minute freeze-thaw cycles are applied. Cryoablation is done on both sides of the coccyx.

Intercostal Cryoablation

Intercostal cryoablation may be indicated for post thoracotomy pain or management of chronic pain syndrome such as intercostal neuralgia. For thoracotomy patients, cryoablation may be done prior to closure of the surgical wound. The intercostal nerve at the level of incision plus two nerves above and below it are cryoablated at -60 degrees centigrade for approximately one minute under direct vision. The freeze-thaw cycle may be repeated one more time. This usually provides analgesia for as long as 30-90 days and patients have less pain compared to those who did not receive this procedure.²⁰

Chronic intercostal pain from postherpetic neuralgia, scar neuroma, nerve root pain from vertebral collapse and carcinoma can be treated by intercostal nerve cryoablation. However, cryoablation for postherpetic neuralgia is only marginally successful.²¹ The procedure can be done using a paravertebral intercostal approach or a more distal approach, depending upon the site of the pain.

The patient is placed under prone position. A mild anxiolytic agent may be given. Non-invasive monitors are put in place. Vital signs are monitored every five minutes during the entire procedure. Fluoroscopic guidance is preferable. The back is aseptically prepped and draped. If a thoracic paravertebral intercostal cryoablation is contemplated, the skin and underlying soft tissues are locally infiltrated with a local anesthetic close to the spine at the point of connection between the rib and the thoracic spine. A scalpel blade #11 is used to make the skin incision. A gauge 12 angiocatheter needle is inserted through the skin incision into the inferior border of the rib under fluoroscopy. Once the needle comes in contact with the rib, the stylet is removed and a gauge 14 cryoprobe is inserted into the outer cannula and the cryoprobe is walked under the rib at an angle of 45 degrees. Although preliminary nerve stimulation is not required, I prefer to activate my nerve stimulator to demonstrate whether I can replicate the pain. The area is then frozen and thawed in the same manner (duration and number of cycles) as described during cervical cryoablation. Alternatively, intercostal cryoablation can be done distally. The most common site is at the angle of the rib located approximately 4-6 cm lateral to the spinous process of the thoracic vertebra. A potential problem is the development of pneumothorax.

Conclusion

Cryoanalgesia is gaining acceptance as one of the more innovative means of relieving pain. It promotes analgesia by destroying neural elements through formation of intracellular ice crystals. It does not disrupt the neural tubes thus allowing nerves to regenerate in an orderly fashion, preventing the development of post-procedural neuritis. Cryoablation is indicated in a variety of painful conditions including cancer and a multitude of non-malignant chronic pain such as facial, back, neck, perineal and extremity pain. The procedure is relatively safe, minimally invasive, and is useful in painful conditions that do not respond to conservative means.

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