Cryogenic Neuroablation for the Treatment of Lower Extremity Neuromas

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A prospective study testing the efficacy of cryosurgery on lower extremity neuromas was performed. Thirty-one neuromas in 20 patients were percutaneously denervated using a Westco® Neurostat-III cryoneedle. All patients were surgical candidates who had failed prior conservative treatment. Patient evaluation consisted of a 10-point visual analog scale (VAS) that was administered pre- and postoperatively. Periodic evaluation with the VAS and patient satisfaction was conducted for a 1-year period following the procedure. Immediately after the procedure, all patients reported complete relief of pain and were permitted to return to full activity. Two weeks after the index procedure, patients were categorized into one of three groups: those who remained completely pain free (38.7%), those who had reduced pain (45.2%), and those who had reverted to preprocedure pain levels (16.1%). The pain score of those patients who had reduced pain decreased from a mean of 8.5 ± 0.4 preprocedure to 3.5 ± 0.4 ($p < .002$). All five patients with no improvement had previous local neurectomies. Even though fewer than 40% of the patients had complete pain relief, an overwhelming 90% stated they would have the procedure performed again. Cryogenic neuroablation appears to be a viable treatment option for patients with lower extremity neuromas. The success rate is similar to surgical excision with little to no disability period and high patient satisfaction. (The Journal of Foot & Ankle Surgery 41(5):286–290, 2002)

Key words: cryoanalgesia, cryosurgery, neurectomy, neuroma

A neuroma is a progressive, degenerative enlargement of a nerve that is often associated with severe lancinating pain, numbness, cramping, and eventual loss of function. Symptoms can become debilitating, limiting patients' daily living activities and reducing their quality of life (1). It is one of the most common conditions encountered by foot and ankle surgeons. There have been numerous publications that have addressed etiological and pathological factors of neuromas in the lower extremity, and especially in the foot (2–11). Possible etiologies include trauma, pedal morphology, and repetitive biomechanical stress. Conservative treatment options include wider shoe gear, nonsteroidal anti-inflammatories (NSAIDs), corticosteroid injections, and accommodative orthotics. Surgical excision is usually reserved for patients who fail to respond to conservative treatment and involves resection of the pathological nerve tissue. The failure rate of surgical neurectomies exceeds 20% (12–16). The neuroma may recur at its resected margins, a complication that can occur anytime the nerve sheath is disrupted (8, 17, 18). Traumatic amputation or stump neuromas often present with the same or worse symptomatology, and may require revisional surgery (10, 11, 14, 16, 18).

Cryotherapy to relieve pain is not a new concept. Hippocrates recognized the analgesic and anti-inflammatory properties of ice on injuries (19). Cryogenic neuroablation is a minimally invasive technique that uses extremely low temperatures to destroy nerve endings. With the advent of the Joule–Thompson enclosed gas expansion cryoneedle, cryoanalgesia to treat pain disorders has become more common (16). Tissue is frozen by exploiting the Joule–Thompson effect within the probe (Fig. 1). The free expansion of nitrous oxide in the cryoprobe tip rapidly drops local tissue temperature to approximately −70°C. The 5.5-mm ice ball formed at the probe tip destroys the nerve tissue and causes extensive vascular damage to the endoneurial capillaries or vas nervorum. This in turn initiates demyelinization and subsequent Wallerian degeneration of the axon. Because the perineurium and epineurium are preserved, amputation neuroma formation is prevented (4, 7, 13, 16, 17).

Application of this technique to neuromas of the foot has not been extensively evaluated. To examine the efficacy of cryogenic neuroablation on lower extremity neuromas, we prospectively studied patients' responses to the procedure.

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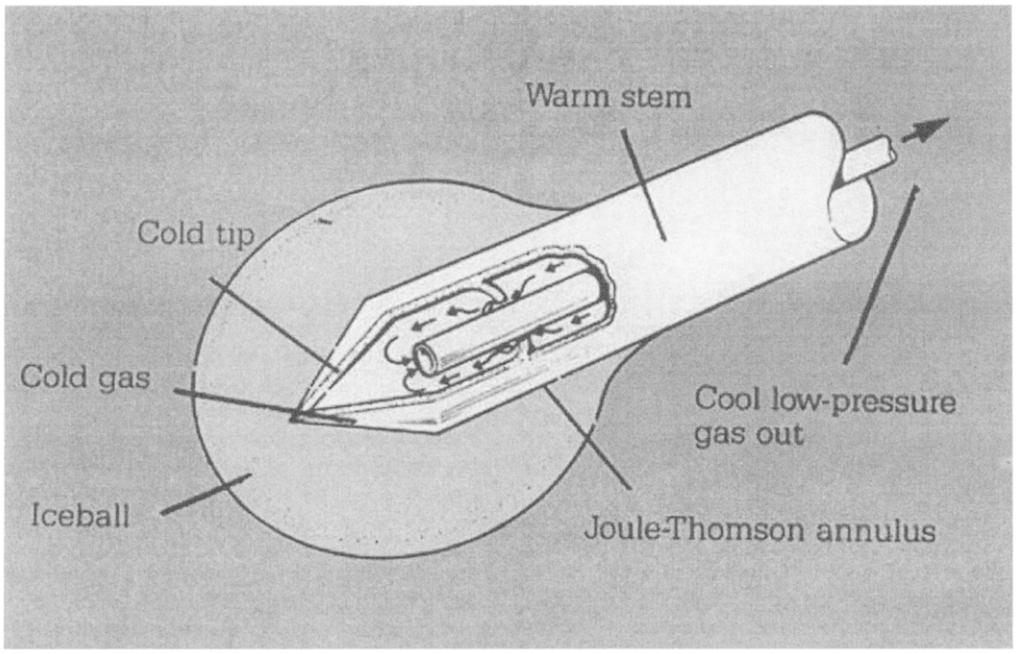

FIGURE 1 The Joule–Thompson effect. Nitrous oxide or carbon dioxide is passed through a central aperture within the tip of the cryoneedle. The gas is then rapidly drawn back through the needle via a vacuum system. Free expansion of gas in the probe tip rapidly drops the temperature in the local tissues to approximately −70°C, thus creating an ice ball measuring approximately 5.5 mm. (Figure Courtesy of Westco Medical Corporation, San Diego, CA.)

Materials and Methods

Patients were recruited from within the Oakwood Healthcare System with an established diagnosis of a lower extremity neuroma. All patients had previously failed conservative treatment and were facing surgical excision as the next phase in treatment. Some patients had already failed surgical excision of their neuroma(s). All patients gave informed consent prior to their inclusion and completed a short questionnaire to collect demographic information. Patients were then asked to rate their pain both pre- and postprocedure using an 11-point visual analog scale (VAS) (0–10; 1 cm between each whole number), where 0 was pain free and 10 was the worst pain they had ever experienced.

Thirty-one neuromas, in 20 patients, were treated using a Westco® Neurostat-III[4] cryoneedle. All cryoablations were carried out as office procedures. The procedure involved anesthetizing the overlying skin with approximately 0.5 cc of xylocaine injected subcutaneously. Care was taken not to anesthetize the underlying neuroma. A 12-gauge cannula was then passed percutaneously into the vicinity of the symptomatic nerve. A nerve stimulator, located in the tip of the cryoneedle, was activated to elicit a pain response. Several short activations ensured that the probe was as accurately placed near the nerve as possible. Each nerve then underwent two 3-minute freeze cycles with a 30-second thaw period interspersed. The nerve stimulator was again activated to determine if there was any residual pain. If there was, the procedure was repeated. Once the pain response was eliminated, a dry, sterile dressing was applied to the operative site, and the patient left the office and was instructed to resume normal activity. No narcotic pain medications were prescribed for postoperative pain. Patients were instructed to use over-the-counter NSAIDs for any discomfort.

Patients were contacted by phone at regular intervals (1 day; 1, 2, and 4 weeks; then monthly) for 1 year. The VAS pain rating was repeated during each encounter. They were also asked to characterize their satisfaction with the surgical outcome as either: satisfied with no reservations, satisfied with minor reservations, satisfied with major reservations, or completely dissatisfied.

Statistical Analysis

Individual pain ratings prior to and immediately after the procedure were compared by paired *t*-test. Once the patient's response to the procedure became clear (14 days postprocedure; pain-free, reduced pain, and no pain relief), comparison over time from days 0 to 336 was performed using repeated measures analysis of variance (rmANOVA). Significant differences were indicated by a p value $<.05$.

[4] Westco Medical Corporation, San Diego, CA.

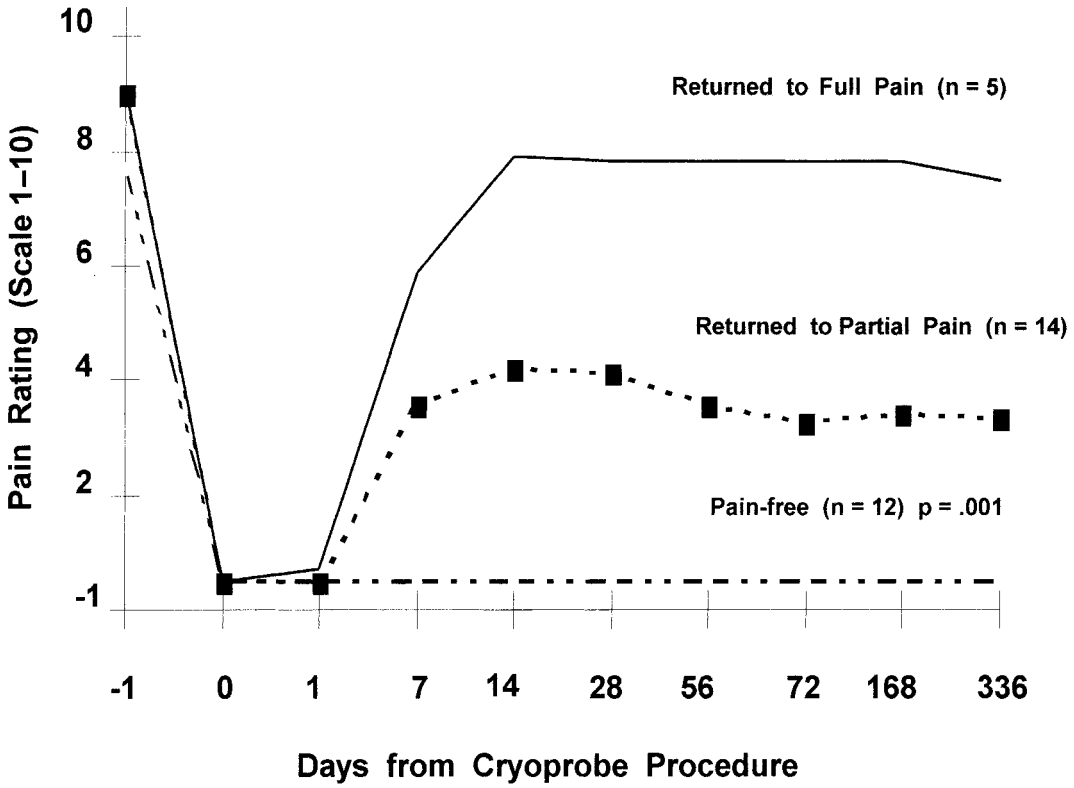

FIGURE 2 Pain ratings by type of response to cryoprobe ablation. Pain ratings differed between patients with reduced versus those who returned to preprocedure pain (rmANOVA, $p < .002$) and those who were pain free versus partial pain relief and preprocedure pain ($p < .05$). Cryosurgery was completely effective (pain free) for 38.7% ($n = 12$), partially effective for 45.2% ($n = 14$), and completely ineffective (return to preprocedure pain level) for 16.1% ($n = 5$). For the reduced pain group, there was a significant decrease in pain from a mean preprocedure pain rating of 8.5 ± 0.4 (SE) to an average postprocedure score of 3.1 ± 0.4. A reliable predictor of the efficacy of cryosurgery was pain rating at 14 days postprocedure, where all of the patients fell into one of the three pain groups.

Results

Neuromas were located in the intermetatarsal space (28 neuromas), on the intermediate dorsal cutaneous nerves (two neuromas), or the sural nerve (one neuroma). There were 17 female patients and three male patients; mean age was 54.4 ± 2.8 (mean ± SE), with a range of 28–72. Immediately postprocedure, all patients were completely pain free (VAS rating of 0) (Fig. 2), and all patients returned to full activity.

Patient pain ratings over the course of 1 year are shown in Figure 2. Two weeks postprocedure, all of the patients fell into one of three groups: completely pain free, partial pain relief, and return to preprocedure pain level. Pain ratings differed between patients with partial relief versus unreduced pain ($p < .002$) and those who were pain free versus partial relief and unreduced pain ($p < .05$). Cryosurgery was completely effective for 38.7% of these patients (pain free; $n = 11$), and partially effective for 45.2% ($n = 15$). Only 16.1% of the patients did not get any pain relief from the procedure ($n = 5$). In the partial relief group there was a significant decrease in pain from a mean preprocedure pain rating of 8.5 ± 0.4 (SE) to an average postprocedure score of 3.1 ± 0.4. Patient satisfaction with the cryoprobe procedure was also followed over the course of 1 year (Fig. 3). Sixty-five percent of the patient population was completely satisfied or had only minor reservations about the procedure, and 35% had major reservations or were completely dissatisfied. An overwhelming 90% of patients stated they would have the procedure performed again.

Discussion

Cryoablation has been used by many other specialists to ameliorate neuroma pain. To our knowledge, there is only one other report of cryoablation of lower extremity neuromas (16). In recalcitrant cases of neuroma, surgical resection has been the usual form of treatment with success rates up to 85% good to excellent results (20). Comparable success has been noted for 4% alcohol sclerosing injections (21). In this study, a percutaneous cryosurgical procedure was performed to destroy peripheral nerves. Based on a VAS, the authors were able to show that cryosurgery attained a success rate (90%) comparable to traditional surgery, without the subsequent

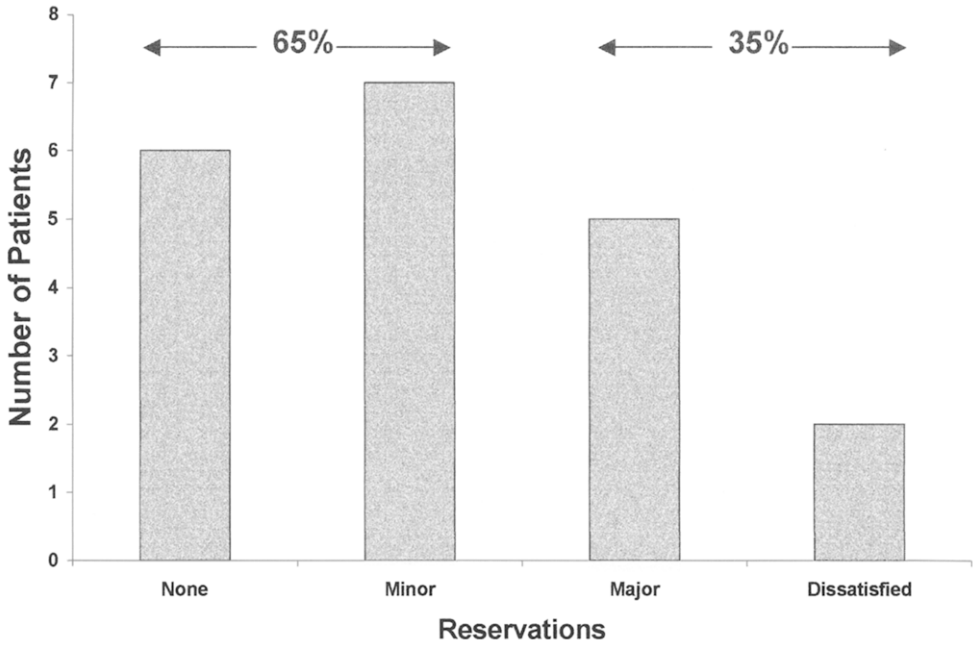

FIGURE 3 Patient satisfaction with cryoablation. Sixty-five percent of the patient population was completely satisfied or had only minor reservations, while 35% had major reservations or were completely satisfied. Ninety percent of the patients stated they would have the procedure performed again.

disability. We also found that most of our patients were satisfied with the procedure, and none reported subsequent side effects.

This study has several weaknesses. Because we could not justify a randomized study of the cryoprobe versus traditional surgery without knowledge that the cryoprobe would be effective in relieving neuroma pain, patients in the current study all purposely treated by the cryoprobe. Since all patients were from our practice, and we performed all the procedures, it is possible that the patients under-rated their postprocedure pain and over-rated their satisfaction in a conscious or unconscious effort to please us. As such, we are in the process of performing the randomized study that will allow appropriate comparison of the two techniques. In addition, several patients had growths on two adjacent nerves treated at the same time, and may have been unable to distinguish between the two when they rated their pain. Finally, our follow-up stopped at 1 year, which is too short of an interval to determine whether subsequent nerve growth would result in symptoms.

High-risk patients who would normally not tolerate an open surgical procedure should achieve the greatest benefit from cryosurgical nerve ablation. It also appears to be less costly than traditional surgery, since there are no hospital facility fees, anesthesia charges, or operating room fees.

All of the patients who had no relief of pain following cryosurgery had previous surgery in the area. The authors feel that fibrosis and scar tissue from previous surgery may have prevented complete penetration of the cryolesion and may be a limitation of the procedure. A larger study will be necessary to evaluate this possibility properly.

Summary

Cryogenic denervation should be considered as a viable treatment option for symptomatic neuromas of the lower extremity. The procedure can be done in the physician's office and has little to no disability period. It seems to offer similar relief to that of traditional surgery without the potential risks that are associated with surgery, but a randomized trial will be necessary before the two can be directly compared.

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