Low-intensity Laser Therapy and Transcutaneous Electrical Nerve Stimulation in the Treatment of Diabetic Peripheral Neuropathy

Abstract

- **Background:** Peripheral neuropathy affects over 20 million people in the United States. Diabetic peripheral neuropathy is a common complication of diabetes mellitus. Nearly 60 % of diabetics develop the condition. Pharmacologic approaches are ineffective in reversing the condition. Transcutaneous electrical nerve stimulation (TENS) and Low-intensity laser therapy are beneficial, but may take up to three months to achieve significant results.
- **Methods:** Ten patients with various stages of diabetic peripheral neuropathy were treated with simultaneous application of TENS and LILT. Two completed one session, one completed two sessions, and seven received a total of 3 treatment sessions at 48 hour intervals. Patients were asked to rate their level of numbness, pain, and sensitivity to touch on a 0 to 10 scale, with 10 being the most severe, before and after completing the trial. A neurologic assessment was done before and upon completion of the trial.
- **Results:** Nine of the ten patients had subjective or objective findings at the beginning of the study. Eight of those nine reported improvement after the first treatment. Seven individuals completed all three treatments. Personal ratings improved in six of those seven. Cumulative scores for numbness dropped from 33 to 22, pain from 31 to 13, and sensitivity to touch from 33 to 12. Neurologic testing demonstrated improved sensation in five of the seven who completed three treatments. All ten of the patients stated that they would like to receive additional treatments if they were made available.
- **Interpretation:** The simultaneous application of TENS and LILT treatment modalities brings immediate improvement in diabetic neuropathy. Pain and numbness are further reduced with additional treatments.
- **Conclusion:** The results of this study suggest that simultaneous application of TENS and LILT results in immediate and ongoing improvement in diabetic peripheral neuropathy. The results seen exceeded what is reported when either modality is applied separately.

BACKGROUND

Peripheral neuropathy is a common condition affecting over 20 million people in the United States. Peripheral neuropathy is a common complication of diabetes mellitus. Studies have shown that approximately two-thirds of all diabetics will develop peripheral neuropathy to some degree. Twenty percent of diabetics will complain of symptoms caused by the condition and approximately five percent will experience pain that is severe enough to disrupt their daily activities.

No satisfactory treatment for peripheral neuropathy exists. Drug treatment is limited to relief of symptoms; it will not significantly slow the progression of the disease nor will it reverse the condition once it is present.

Nutritional supplementation with alpha-lipoic acid has been shown to reduce perceived levels of pain, burning, tingling, and numbness, but objective measures such as ankle reflex, pin-prick, and pressure generally remain unchanged. Improvement in symptoms appears gradually over three to eight weeks.

Electromagnetic nerve stimulation and low-intensity laser therapy have shown promise in the treatment of peripheral neuropathy. Improvement is typically seen after 3 weeks to 3 months.

Participants and intervention

Ten patients with documented peripheral neuropathy at a diabetic support clinic were treated with a combination of transcutaneous electrical nerve stimulation (TENS) and low-intensity laser therapy (LILT). TENS and LILT were applied for fifteen minutes at the first session and for thirty minutes in subsequent sessions. Sessions were conducted at 48 hour intervals. A total of three sessions were offered.

Primary outcome measure

The primary outcome measure was reported improvement in pain or numbness by the test subject.

Secondary outcome measures

Secondary measures were objective improvement in clinical tests of touch, pin-prick, position sense, balance, and foot temperature.

RESULTS

Primary outcome

One of the test subjects was referred by the diabetic clinic on the basis of his clinical record. He was asymptomatic prior to treatment and no objective findings of neuropathy were noted. As a result, it was not possible to achieve symptomatic or objective improvement. He commented that the treatments "felt really good".

Of the remaining 9 test subjects 8 reported improvement in symptoms with the initial 15 minute treatment session. In two the improvement lasted for approximately 10 hours. The others reported that the improvement had lasted through their next scheduled treatment.

Seven individuals completed all three treatments. Personal ratings improved in six of those seven. Cumulative scores for numbness dropped from 33 to 22, pain from 31 to 13, and sensitivity to touch from 33 to 12. All ten of the patients stated that they would like to receive additional treatments if they were made available

Secondary Outcomes

Neurologic testing demonstrated improved sensation in five of the seven who completed three treatments. In two of the patients improvement in numbness was dramatic. Both were numb to knee level at the beginning of the trial and both could detect pressure at toe level following the treatment sessions. Position sense was initially abnormal in four individuals who completed the study. Improvements were noted in all four. None of the patients were able to perform a tandem walk before participating, but two could successfully do so after receiving three treatments. No significant change was found in foot temperature.

Tolerability

The only adverse effect reported was mild, transient muscle soreness that did not interfere with activities of daily living. No patient dropped out of the study because of an adverse event.

Individual Patient Results:

Patient 1: This man reported a six year history of neuropathy. He initially rated his numbness a 7, pain a 6, and sensitivity to touch an 8. Prior to treatment he stated that he felt as though he was walking on stumps of wood. He placed his heels in a depression of his recliner at night so that his legs would be elevated because the pain he experienced if his legs rested on a surface prevented him from sleeping. After participating in the study he could feel his legs while walking and he no longer experienced pain when his legs rested on the surface of his chair. He stated that he felt 50 % improved after the first session. His post-study ratings were 4 for numbness, 5 for pain, and 4 for sensitivity to touch. Touch and pin-prick sensation were at knee

level prior to the study and at toe level following his third session. Position sense was diminished in his right toe prior to the study and normal upon completion.

Patient 2: This woman reported a six year history of neuropathy. Her intake history reported numbness at 3, pain at 9, and sensitivity to touch at 9. Tingling and burning were present. Self-reported numbness remained a 3, but pain and sensitivity dropped to 0. Position sense improved and she was able to tandem walk for 3 steps following the study after failing to walk for one step prior to the study. Level of numbness improved from the level of the lower 1/3 of her leg to the mid-foot.

Patient 3: This man gave a 10 year history of neuropathy. He initially reported numbness at 5, pain at 2, and sensitivity to touch at 5. Post-participation ratings were 4 for numbness, 2 for pain, and 2 for sensitivity to touch. Pressure could only be felt in his left 5^{th} toe prior to treatment, but could be detected in toes 3 – 5 bilaterally following. Sensitivity to touch during the examination was much improved. He was the one individual who stated that he did not notice an improvement over the course of the study. Nevertheless, his self-reported numbness and sensitivity scores improved and his neurological examination revealed less sensitivity to touch and return of sensation in several toes.

Patient 4: This man reported neuropathy of three years duration. Prior to the study he stated that his legs were "dead, dead, dead!" He rated numbness a 9, pain a 4, and sensitivity to touch 0 prior to treatment and numbness 5, pain 0, and sensitivity 0 following. He reported more feeling in his toes as a result of the treatments. His level of numbness prior to treatment was his upper leg 7.5 cm. below his tibial tuberosities. At the end of the study he had pin-prick sensation in all toes and touch sensation in the right 5^{th} toe and all left toes. Position sense improved in his right great toe. His post study comments were, "I'm doing better. I have more feeling in my feet and toes."

Patient 5: This man had a 10 year history of neuropathy. His pre-study self ratings were 2 for numbness, 2 for pain, and 1 for sensitivity to touch. Post-study ratings were 1 for numbness, 0 for pain, and 0 for sensitivity. Level of pin-prick detection improved from ankle level bilaterally pre-treatment to toe level on the left and mid-foot on the right post-treatment. He was unable to tandem walk before treatment, but he was able to do so post-treatment. Prior to treatment his feet felt hot and he felt as though he was on small rocks when walking barefooted. He was not experiencing burning and his walking felt better following the treatments.

Patient 6: This man reported neuropathy of 9 years duration. His pre-treatment self-ratings were 7 for numbness, 7 for pain, and 4 for sensitivity to touch. He had difficulty walking due to pain and numbness. Following treatment his self-ratings were 5 for numbness, 5 for pain, and 0 for sensitivity. His sensation of pins and needles had been reduced to tingling. He was aware of pressure only on the little toe of his right foot before treatment, but could detect pressure on his 3^{rd} through 5^{th} toes following treatment. No improvement was found in his left foot.

Patient 7: This man was unable to date the onset of his neuropathy. He reported no numbness, stated his pain as a 1, but rated his sensitivity to touch as a 6. His self-ratings did not change over the course of the study. His neurologic examination did not reveal any abnormalities pre or post treatment. The therapist and examiner both noted marked improvement in his ability to tolerate touch, however.

Patient 8: This man was referred to the study by the diabetic support clinic as someone having peripheral neuropathy. He reported no symptoms and his neurologic examination was normal. He completed two treatments and stated that they "felt good."

Patient 9: This woman reported a 2 year history of neuropathy. Touch sensation was absent in the first 3 toes and ball of her right foot and the big toe and ball of her left foot. She stated that she could feel her toes after the first treatment. Her husband became ill and she was unable to return for the second and third treatments.

Patient 10: This man had a neuropathy of 12 years duration. He rated numbness a 4 and pain a 4. He reported that he was unable to sleep well at night and could hardly stand after sitting for a time because of the neuropathy pain. He could not detect touch in his toes. He was pleased and reported that he could feel a toe after the first treatment. He called to report that he would be unable to return for the second and third treatments, expressing regret and requesting that he be notified if another opportunity became available.

INTERPRETATION

Subjective or objective improvement was obtained in all study participants who presented with symptoms or physical findings of peripheral neuropathy. Eighty-eight percent noticed a benefit with the first treatment. This suggests that the combined administration of transcutaneous electrical nerve stimulation and low-intensity laser therapy is significantly more effective in the treatment of diabetic peripheral neuropathy than either modality used alone.

DISCUSSION

Diabetes is the leading cause of non-traumatic amputation in the United States. A large percentage of amputations result from the individual's inability to sense pain or pressure in a foot. Improved sensation in the feet can potentially eliminate the risk of amputation for many diabetics.

Balance improved in two of the study participants. If this proves to be a consistent benefit of TENS/LILT therapy a large number of hip fractures and other fall-related injuries may be prevented.

Five percent of diabetics develop nerve-related pain that interferes with their daily activities. Drugs are often ineffective in relieving the pain. An effective means of reducing or eliminating pain would provide a marked increase in quality of life for these individuals.

The potential for improvement is great, as estimates place the number of diabetics in the United States at over 18 million. This number is expected to rise significantly. Some predict a threefold increase by 2050.

This study provides evidence that simultaneous TENS and LILT administration is able to provide an immediate reduction in pain and reduce pain to progressively lower levels with subsequent treatment sessions. It also demonstrates that perception of pressure and pin prick can be restored successfully and that this can be accomplished quickly.

The ability of the combined modalities to provide observable benefits immediately in a high percentage of users should result in a high success rate, since individuals are more likely to continue to employ treatments that provide immediate benefit. Combined TENS and LILT administration is superior to other approaches in this regard, as most treatment regimens begin to show improvement only after they have been followed consistently for 3 weeks to 3 months.

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