Monochromatic Infrared Photo Energy and Physical Therapy for Peripheral Neuropathy: Influence on Sensation, Balance, and Falls

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ABSTRACT

Purpose: Elderly patients are at high risk for falls due, in part, to the loss of sensation in the lower extremities. This study examined the effectiveness of a comprehensive therapy intervention that included monochromatic infrared photo energy for improving foot sensation, balance, and fall status. **Methods:** Thirty-eight patients, average age 78 years, participated in this study. All patients lacked protective sensation in the lower extremities (documented by the Semmes Weinstein 5.07 monofilament), demonstrated a significant fall risk based on Tinetti scores, and had a history of falling. Patients participated in a mean 12 treatments that consisted of infrared photo energy, neuromuscular re-education, balance and strength training, and stretching exercises. **Results:** Comparisons of patients' status pre- and post- treatment showed that they improved significantly in lower extremity sensation and balance and that they experienced fewer falls. **Conclusion:** A comprehensive therapy intervention that includes infrared photo energy has the potential to improve sensation and balance and to reduce fall frequency. These results should be of great interest to patients with peripheral neuropathy, health care providers who treat these patients, and the payor community that incurs the cost of treatment.

Key Words: infrared photo therapy, neuropathy, falls, balance, impairments

INTRODUCTION

One in every 3 persons over the age of 65 falls each year.[1,2] Among those over 65, falls are the leading cause of injury, deaths, and hospital admissions for trauma.[3,4] Falls among the elderly are a significant health care concern with associated costs exceeding $20 billion annually.[5] The most significant consequence of falls is hip fracture.[6] In 1996 there were approximately 340,000 hospitalizations for hip fractures[7] and 50% of the older adults were unable to return home or live independently after their hospitalization.[8] By 2020, the cost of falls in the United States is expected to rise to $32 billion per year.[9]

Falls are a consequence of numerous intrinsic (patient centered) and extrinsic (environmental) factors. Intrinsic factors contributing to falls include gait and balance deficiencies, neurological and musculoskeletal impairments, psychoactive medication use, dementia, and visual impairment.[10] The literature also suggests a high correlation between fall occurrence and diminished sensation among patients with diabetic peripheral neuropathy and neuropathy from other causes such as chemotherapy, alcohol abuse, and peripheral vascular disease.[11-13] In fact, individuals with Type 1 diabetes and neuropathy are reported to be 15 times more likely to fall than their diabetic counterparts who do not yet exhibit peripheral neuropathy.[14] Additionally, the risk of injury from falls in elderly patients exhibiting neuropathy may exceed 50%, far more than that of the elderly population as a whole.[15]

The early stages of diabetic peripheral neuropathy are often characterized by pain and tingling. Five years after initial diagnosis of diabetic peripheral neuropathy, diminished appreciation of temperature and/or pressure is evident in the feet of virtually all of these patients.[16] The progressive sensory loss associated with diabetic peripheral neuropathy makes it very difficult, if not impossible, for physical therapists to achieve meaningful improvements in balance, reductions in fall risk, and a decrease in falls (even when using interventional strategies that have proven successful in elderly patients without neuropathy). For this reason, physical therapy interventions designed to reduce the risk of falls in patients with diabetic peripheral neuropathy have focused primarily on development of compensatory strategies such as using canes, walkers, and managing extrinsic (environmental) fall risks.

Kochman et al recently reported that it is possible to significantly improve foot sensation in diabetic patients with peripheral neuropathy, including those with loss of protective sensation. They used a noninvasive medical device, the Anodyne® Therapy System (ATS), which emits monochromatic near infrared photo energy (MIRE™).[17] Their results are a dramatic departure from those of other interventions that have been unable to restore protective sensation in patients with diabetic peripheral neuropathy. The present study was conducted to determine whether the increased sensation achieved using the ATS, integrated with appropriate balance focused physical therapy interventions, would be able to reduce balance/gait deficiencies and reduce the risk of falls in an elderly population.

METHODS

Patients

This study employed data from the records of 38 consective patients attending an inpatient physical therapy clinic. Institutional review board approval was obtained for use of the data. The mean age of the patients was 78 ± 9.4 years (range: 56 to 97). Fifteen patients were male and 23 were female. Twenty-seven patients had a primary diagnosis of diabetic peripheral neuropathy, 6 exhibited distal polyneuropathy associated with long-term use of alcohol, and 5 exhibited impaired distal sensation due to peripheral vascular disease (PVD).

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Measurements

Assessment of impaired foot sensation was documented objectively using a 5.07 Semmes Weinstein Monofilament (SWM). Patients were asked to respond with 'Now' when they were able to sense randomly applied pressure by this monofilament on the great toe, third toe, and the plantar arch. Application of the SWM was conducted in accordance with recommended testing protocols including avoidance of heavily calloused areas, avoidance of patient prompting, and visually blinding the patients to the sites being tested. Consistent with Medicare guidelines, insensitivity to the SWM 5.07 monofilament at either 2 or 3 of the tested sites was considered to be impaired sensation and loss of protective sensation.[16]

Balance and gait abnormalities were assessed using the Tinetti Assessment Tool.[9] This is a widely recognized objective instrument for determining balance and gait deficiencies and assessing the risk of future falls. Higher Tinetti scores (maximum 28) correlate inversely with risk of falls. Individuals with Tinetti scores under 19 are considered to be at the highest risk for falls, those with scores between 19 and 24 are considered to have a moderate risk of falling, and those with scores 24 and above are considered to be at low risk for falls. All patients presented with a Tinetti score of 20 or less and thus were characterized as having a known fall risk.

All patients were interviewed to determine a prior history of falls during the 3 months immediately prior to evaluation and treatment. At least one fall during this 3-month pretreatment period was documented for all patients. Seventy-nine percent of the patients experienced two or more falls during the prior 3 months; several had fallen 4 to 6 times.

Intervention

The ATS used in this study is a photo diode (wave length 890 nm) based photon therapy modality that was cleared by the FDA in 1994 for temporarily increasing local circulation and reducing pain. The ATS has been used extensively in the physical therapy department since its purchase by our hospital.[17] Previous research has documented improved wound healing[18] and increased nerve conduction velocity[19] with use of monochromatic infrared energy. The interventional protocol consisted of a daily 30 to 40 minute treatment with the ATS (2 diode containing therapy pads, 1 on the medial and 1 on the lateral side of each lower extremity) followed by physical therapy depending on the assessed needs of the individual patient. The physical therapy interventions consisted of static and dynamic balance retraining, neuromuscular re-education, strength training, and stretching of the ankle plantar flexors and hip flexors. Patients received treatment with ATS and physical therapy until sensation and Tinetti scores increased. The number treatments ranged between 6 and 20. Typically, 12 treatments were required, but those who exhibited less balance impairment required fewer treatments (6) and those with profound balance impairment required as many as 20 treatments.

At the conclusion of treatment patients were examined again using the 5.07 SWM and the Tinetti scale. Subsequently, and with no further ATS or physical therapy interventions, all patients were contacted to determine if they experienced a fall during the 3 months after the completion of treatment.

Data Analysis

After the calculation of descriptive statistics, differences in pre- and post-treatment status were compared using Wilcoxon matched pairs signed ranks tests. Significance was accepted when $P<0.05$.

RESULTS

At baseline, all of the 38 patients exhibited loss of protective sensation assessed by the SWM 5.07 monofilament. The mean number of sites sensitive to the SWM 5.07 (out of 3 tested sites) was 0.9 ± 0.3. The mean Tinetti score was 11.2 ± 4.5 at entry (range: 5 to 20), well below a score of 19, the cut off value below which patients have the highest risk for falls. Finally, the mean number of falls experienced by all patients over the previous 3 months was 2.6 ± 1.4 (range: 1 to 6); there was a total of 98 falls in the 38 patients during the 3 months prior to pretreatment examination.

At the conclusion of the 12.7 ± 2.9 interventions (range 6-20) with the ATS and appropriate physical therapy, all patients demonstrated restoration of protective sensation as determined by the SWM 5.07 monofilament. Specifically the patients were able to sense a mean of 2.7 ± 0.4 of the 3 sites on the foot ($P < 0.0001$). After treatment patients' Tinetti scores were 21.6 ± 3.4. Each patient demonstrated a higher Tinetti score (Figure 1) with a mean improvement of 10.4 ± 3.9 points (range: 4 to 21). This increase was significant ($P < 0.0001$). Additionally, 29 of 38 patients reduced their Tinetti fall risk category by at least one level (for instance, from high risk of falling to moderate risk) and 12 of these experienced a 2-level reduction in fall risk category (Figure 1). Finally, follow up patient interviews showed that only 4 patients experienced a single fall each during the 3-month period following therapy (Figure 2). The average falls per patient (0.1 ± 0.3) represented a significant decrease ($P < 0.0001$).

DISCUSSION

In the present study, it was hypothesized that comprehensive physical therapy intervention consisting of using both

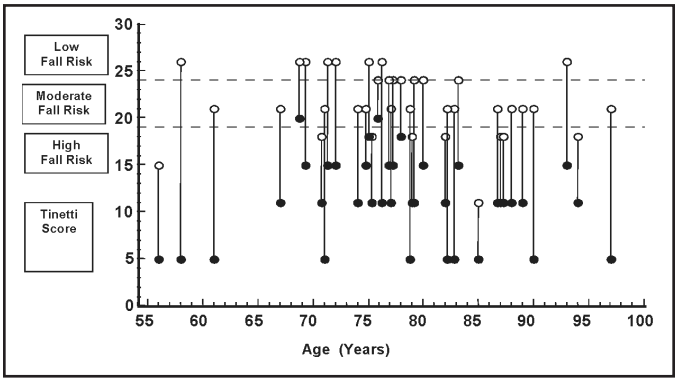

Figure 1. Tinetti scores increase in every patient regardless of age. Filled circles indicate Tinetti scores before ATS and PT interventions and open circles indicate scores after interventions.

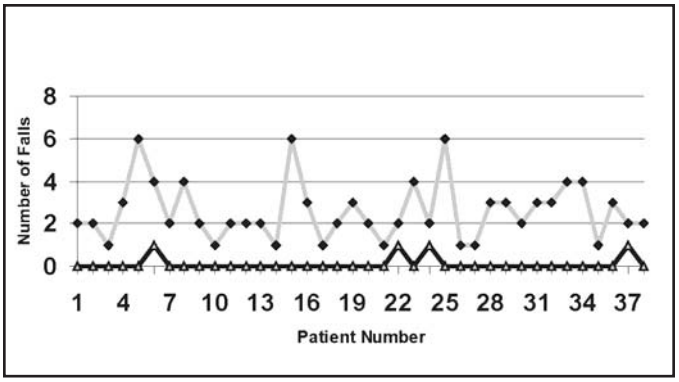

Figure 2. Number of falls by each patient is decreased in the 3 months after combined ATS and PT interventions (triangles) compared to the 3 months before (diamonds).

the ATS to improve sensation and appropriate physical therapy to improve balance, motor control, strength, and flexibility could reduce both fall risk and the post-treatment falls in an at-risk population. This hypothesis was intuitive since interventional strategies that are not accompanied by increased foot sensation in patients with distal neuropathy have produced limited benefit in fall related outcomes.[20]

All patients obtained objective improvement in foot sensation, which was accompanied by significant reduction in objectively measured fall risk (mean Tinetti improvement 10.2 points). Further, this increased sensation and reduced fall risk resulted in a 93% reduction in the actual incidence of falls during the 3 months after treatment when compared to the fall history during the 3 months prior to treatment. Prior to treatment the 38 patients had reported 98 falls and during the 3 months after intervention only 4 falls were reported.

We used the ATS to increase circulation and improve foot sensation in the patients. The ATS is a photon energy based therapeutic device that delivers solely near infrared photo energy (890 nm) produced by diodes. Photo energy, while of limited but rapidly increasing use in the United States, is a well-recognized therapeutic agent internationally, based on published clinical and scientific evidence.[21] Photon therapy is used clinically to increase circulation, reduce pain, and promote healing for a wide variety of conditions.[21] While the underlying mechanism of action is not completely understood, effectiveness is based upon scientific and physiologic parameters including wavelength, energy density, absorption, and duration of treatment[21] and similar wavelengths do increase microcirculation.[22] While there are other photon therapy devices available for use in the United States, we used the ATS due to availability, our staff's years of clinical experience with the ATS, and the existence of a published clinical study that demonstrated the efficacy of ATS in symptomatically reversing diabetic peripheral neuropathy.[17]

Historically, physical therapy interventions designed to reduce the number of falls in elderly patients, particularly those with distal neuropathy, have resulted in minimal success.[23,24] However, Richardson and colleagues[25] have reported that a 3- week exercise program designed to increase rapidly available distal strength and balance in patients with peripheral neuropathy was able to improve unipedal and tandem stance times by a mean of 6 seconds each and functional reach by a mean of 1 inch. However, no analysis of postintervention falls or a broader analysis of changes in gait and balance under a Tinetti and similar test were undertaken. While the therapy intervention in this study included many of the exercises employed in the Richardson study,[25] our protocol included a broader range of gait and balance interventional strategies. Unfortunately, the differences in measures undertaken in our study and the Richardson study[25] make comparison of the therapeutic results and net health outcomes impossible.

Of interest, in this study the loss of protective sensation was due to 3 different etiologies, suggesting that this approach may work to the advantage of the therapist in treating patients with impaired lower leg sensation and proprioception due to various etiologies.

Decreased microcirculation apparently underlies sensory impairment in diabetic patients[26] and is the contributor to wounds and amputations.[27] It is likely that the alcohol and PVD mediated decreases in sensation also are due to poor microcirculation to the endoneurial surface of nerve bundles. These data suggest that improving local circulation and foot sensation, at least with the use of the ATS, improves the efficacy of several important physical therapy interventions designed to improve balance, muscle strength, and gait. This comprehensive treatment approach to balance deficiencies associated with diabetic peripheral neuropathy and other sensory neuropathies is apparently able to significantly improve balance and gait, significantly reduce objective measures of fall risk and, at least for a period of 3 months after treatment reduce the number of actual falls.

Certain limitations of the study design should be considered when analyzing these conclusions. These data were based upon an IRB approved review of patient's charts, thus there was no control. Additionally, concomitant analysis of the utilization of psychoactive drugs and other intrinsic falls risks was not performed. Incidence of falls was only analyzed for brief periods of 3 months before and after interventions. Lastly, the study methodology did not permit us to analyze gains that were attributable to physical therapy alone and those related to the increases in foot sensation resulting from the use of the ATS. Further studies should consider matched controls to: (1) determine the relative effectiveness of the combination of ATS with physical therapy compared to physical therapy alone, (2) control for other intrinsic risks for falls, and (3) follow up on fall outcomes beyond 3 months.

CONCLUSIONS

Based on these clinical data, ATS is able to improve foot sensation, and when used in conjunction with physical therapy is able to significantly improve balance and gait, reduce objective fall risk, and reduce the incidence of falls in an elderly population when comparing 3 month periods immediately before and immediately after intervention.

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