

Reversal of diabetic peripheral neuropathy with phototherapy (MIRE™) decreases falls and the fear of falling and improves activities of daily living in seniors

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Abstract

Objective: to determine whether restoration of sensation, impaired due to diabetic peripheral neuropathy (DPN), would reduce the number of falls and the fear of falling and improve activities of daily living (ADL) in a Medicare-aged population.

Design: retrospective cohort study of patients with documented, monochromatic near-infrared phototherapy (MIRE™)-mediated, symptomatic reversal of DPN.

Setting: responses to a health status questionnaire following symptomatic reversal of DPN.

Patients: 252 patients (mean age 76 years) provided health information following symptomatic reversal of diabetic neuropathy (mean duration 8.6 months).

Main results: incidence of falls and fear of falling decreased within 1 month after reversal of peripheral neuropathy and remained low after 1 year. Likewise, improved ADL were evident soon after reversal of peripheral neuropathy and showed further improvement after 1 year. Overall, reversal of peripheral neuropathy in a clinician's office and subsequent use of MIRE™ at home was associated with a 78% reduction in falls, a 79% decrease in balance-related fear of falling and a 72% increase in ADL ($P < 0.0002$ for all results).

Conclusions: reversal of peripheral neuropathy is associated with an immediate reduction in the absolute number of falls, a reduced fear of falling and improved ADL. These results suggest that symptomatic reversal of diabetic neuropathy will have a substantial favourable, long-term socioeconomic impact on patients with DPN and the Medicare system, and improve the quality of life for elderly patients with diabetes and peripheral neuropathy.

Keywords: diabetic peripheral neuropathy, MIRE™, falls, fear of falling, activities of daily living, Anodyne® therapy system, elderly

Introduction

Diabetes affects more than 15% of the US population over 65 years of age [1]. The direct cost of diabetes exceeds \$91 billion, with more than 51% of this being spent on those over 65 years of age [2]. One complication of diabetes is diabetic peripheral neuropathy (DPN), characterised by diminished sensation, with or without pain, in the lower extremities. DPN affects 30–100% of all long-term diabetic patients depending upon the clinical assessment(s) used to document DPN. DPN is acknowledged as a very significant risk factor for development of diabetic foot ulcers [3] and a major reason for the poor healing rates of these ulcers [4]. Additionally, DPN contributes to gait and balance problems, falls and the fear of falling [5–7]. More specifically, DPN is accompanied by postural instability, loss of available

ankle strength, diminished proprioceptive thresholds both in foot and ankle inversion/eversion and in plantar flexion/dorsiflexion [8]. These complications result in a significant risk factor for falls in patients with DPN compared to diabetics who do not yet have DPN [9].

The risk of falls invariably increases with age and comorbidities [10, 11]. More than 30% of people over 65 years of age will fall one or more times per year [12] and the economic cost of falls exceeded \$20 billion in 1994 [13]. Falls are the fourth leading cause of death in men between 65 and 85 years of age and the leading cause of death among both men and women over 85 [14]. Those with DPN have more impairments in balance [5, 7, 15, 16], an increased risk for falls [5], a higher absolute incidence of falls possibly exceeding 50% [5] and falls that result in injury than the elderly population in general [10]. The increased fear of falling in those with DPN decreases activities

of daily living (ADL) and increases the risk for subsequent falls in people over 65 years of age [17, 18].

While reversal of DPN would theoretically reduce the number of falls and/or fear of falling, and improve ADL, currently there are no pharmacologic treatments for DPN and the progressive health risks it presents that would allow testing of this hypothesis. Certain selected patients with DPN have responded well to a surgical procedure that releases the compression of nerves in the feet, but not all patients are candidates for surgery [19]. Several recent studies [20–26] have reported at least temporary symptomatic reversal of DPN during treatment with monochromatic near-infrared photoenergy, known as MIRE™, which was delivered non-invasively by the Anodyne® Therapy System (ATS; Anodyne Therapy LLC, Tampa, FL 33626, USA), an FDA cleared medical device [27]. To date no studies have examined whether these effects are sustained after treatment with MIRE™ in a clinic is stopped but is continued over time at home. The present study assessed the actual number of falls, the fear of falling, and ADL in 252 patients from 1 to 15 months after they had stopped receiving MIRE™ treatments in a clinic where improved sensation had been documented.

Methods

We administered a health status questionnaire to certain patients with DPN identified from the insurance billing records of two durable medical equipment (DME) suppliers, who had provided to patients an ATS, an item of DME delivering MIRE™, for use at home. The DME providers examined their database for all insurance claims filed under HCPCS code E0221 with dates of service between January 2002 and 31 March 2003 and extracted all claims in which the prescribing diagnosis was diabetic neuropathy using ICD-9 codes 250.61 or 250.62 as indicative of either type 1 or type 2 diabetes, and ICD-9 code 357.2 as indicative of peripheral neuropathy. Next, the medical records, including written physician orders and treatment notes, for each patient were reviewed to confirm the initial diagnosis of DPN with loss of protective sensation (LOPS) and the subsequent improvement in sensation after treatment with MIRE™. The diagnosis was based on a history and physical documentation by the attending physicians. While many tests were described in the underlying clinical records, the presence of sensory impairment prior to the treatment and improvement after treatment were documented using the SWM 5.07 monofilament test. The SWM is recommended by the National Institutes of Health in Feet Can Last a Lifetime [28] and is the test of choice to determine LOPS by Medicare [29]. If a patient cannot feel the monofilament on two of five tested sites on either foot using a forced-choice test, they are considered by Medicare to have DPN.

Improvement in DPN symptoms following treatment with MIRE™ by physicians formed the basis for acquiring an ATS for use at home. This medical record review also indicated that neuropathic pain had decreased in many of these patients after instituting MIRE™ treatments. Lastly,

claims for all patients younger than 64 years were excluded to permit analysis of only the Medicare-aged population.

Using these selection criteria, the medical records demonstrated clinical documentation for reversal of DPN after use of MIRE™ in 369 patients. The patients were contacted by the DME suppliers to ascertain if they would be willing to participate in a telephone questionnaire. The questionnaire elicited information regarding fall history, fear of falling and ADL, prior to and after reversal of DPN and LOPS.

The following questions with respect to the period prior to receiving successful treatment with the ATS (reversal of DPN and LOPS) were:

- (i) Did you feel off balance to the extent that you feared falling when you walked?
- (ii) How many times did you fall during the 12 months prior to the time you started using Anodyne®? (None, 1 time or 2 or more times).

Questions related to the period after reversal of DPN and LOPS were:

- (iii) Do you feel that your balance has improved and that you now have less fear of falling when you walk?
- (iv) How many times did you fall since the time you started using Anodyne®? (None, 1 time or 2 or more times).
- (v) Compared to what you were able to do most days before using Anodyne®, how would you compare what you are now able to do most days? (A lot less, A little less, About the same, A little more, A lot more).

Evidence of balance impairment and fear of falling associated with DPN was determined based on the patient's response to question (i) and improvement after reversal of DPN was determined by response to question (iii). Falls associated with DPN were determined by the answer to question (ii) and a change in fall incidence after reversal of DPN was determined based on the answer to question (iv). Changes in ADL were determined based on the response to question (v). Lastly, the health status questionnaire included a comment section where the patients could relate, at their discretion, any additional information.

Eight interviewers attempted contact with the 369 successfully treated patients. Contact was attempted at least three times to maximise the number of responses. A total of 252 out of 369 (68%) community-dwelling patients completed the questionnaire, providing us with data covering a period of ATS usage ranging from 1 to 15 months (average 9 months) after reversal of DPN. For purpose of analysis, we then stratified these patients into five groups: those who had used ATS for (i) 1–3 months, (ii) 3–6 months, (iii) 6–9 months, (iv) 9–12 months and (v) 12 or more months after reversal of DPN.

Statistics

Data were analysed by paired two-tailed *t*-test with a null hypothesis that reversal of DPN would have no effect on (i) the number of falls, (ii) balance improvement and fear of falling or (iii) ADL irrespective of the numbers of months of ATS use. The two-tailed *t*-test was employed because we made no assumption (a priori) as to the direction changes would occur, if at all. Significance was accepted when $P < 0.05$. The statistical package StatView™, from Abacus

Concepts, Inc., Berkley, CA, was used. Values are expressed as mean (SD).

Results

The mean age of the 252 patients (138 males) was 75.4 (6.6) years (range 64–101). Sixty-three patients were 80 years or older and 41 were between 64 and 69. Utilisation of the ATS at home by these community dwellers averaged 8.6 (4.2) months (range 1–15 months). Table 1 describes demographics for the 252 diabetic patients and Table 2 describes the outcomes in each of five groups (1–3 months, 3–6 months, 6–9 months, 9–12 months and 12+ months of ATS use). The following results were obtained.

Number of falls

During the year prior to clinical reversal of DPN, 73 of the patients (29%) had fallen and 53 of these (73%) experienced two or more falls. In the period after reversal of DPN, 57/73 (78%) patients reported a decrease in the number of falls ($P<0.0001$), either from one to none or from two or more to one or no falls. As anticipated, patients in the 1- to 3-month group showed the highest reduction in falls (100%); however those in the 12-month or longer group showed the second highest reduction in the number of falls (83%, Table 2). All groups reported a reduction in fall incidence. During the approximately 9 months after reversal of DPN, only 33/252 patients (13%) experienced a fall compared to 73/252 (29%) who had fallen during the year prior to reversal of DPN. This represents a 55% reduction in the number of patients reporting a fall after reversal of DPN ($P<0.0001$).

Fear of falling

Prior to reversal of DPN, 166 out of 252 patients (66%) reported being off balance to the extent that they feared falling when they walked. After reversal of DPN, 35 of these patients continued to report fear of falling when they walked whereas 131 of these patients (79%, $P<0.0001$)

reported substantial improvement in balance and a reduced fear of falling. Patients in all groups reported a reduced fear of falling ranging from a high of 92% in the 1- to 3-month group to a low of 65% in the 12-month and greater group ($P<0.0001$ in all groups, Table 2).

Activities of daily living

After reversal of DPN, 182 out of 252 patients (72%, $P<0.0001$) reported they were able to at least ‘do a little more most days’ than they were when they suffered from DPN and 80 of these (44%, $P<0.0001$) reported being able to ‘do a lot more most days’ compared with when they suffered from DPN. Improvement in daily living was reported by patients in all groups with a high of 77% in the 6- to 9-month group and a low of 67% in the 3- to 6-month group ($P<0.0001$ for all groups). The percentage of patients able to do a lot more after reversal of DPN was highest in the 6- to 9-month group (59%) and was lowest in the 12-month and longer group (31%, $P<0.0001$ for all groups, Table 2).

Neuropathic pain

The medical records indicated that 220 out of 252 patients (87%, $P<0.0001$) obtained substantial reduction in neuropathic pain in addition to improved foot sensation after reversal of DPN. Reduction in pain was reported in all groups with a high of 95% in the 1- to 3-month group and a low of 76% in the 3- to 6-month group ($P<0.0001$ for all groups, Table 2).

Discussion

Prior studies have shown DPN to be a major contributory factor to balance impairment and falls in diabetic patients [10]. Our analysis confirmed the existence of both balance impairment and fall history in the diabetic patients we surveyed. Importantly, the present data demonstrate that reversal of DPN, at least with MIRE™, may substantially

Table 1. Patient demographics

| | | |
|--|------------|---------|
| Patients contacted by phone (<i>n</i>) | 369 | |
| Patients responding to questionnaire ^a (<i>n</i>) | 252 | |
| Percentage of patients responding | 68 | |
| Males | 138 | |
| Females | 114 | |
| Age (years) ^b | 75.4 (6.6) | |
| Average months with reversal of DPN | 8.6 (4.2) | |
| Patients who fell before reversal of DPN | 73 | |
| Patients with two or more falls | 53/73 | <0.0001 |
| Patients with fewer falls after MIRE™ | 57/73 | <0.0001 |
| Total falls after MIRE™ | 13/252 | <0.0001 |
| Feared falling before reversal of DPN | 166 | |
| Feared falling after reversal of DPN | 35 | <0.0001 |
| No longer feared falling after MIRE™ | 131 | <0.0001 |
| ADL after reversal of DPN | | |
| Able to do a little more | 182/252 | <0.0001 |
| Able to do a lot more | 80/182 | <0.0001 |
| Pain reduced after reversal of DPN | 220/252 | <0.0001 |

n, number of patients; DPN, diabetic peripheral neuropathy; MIRE™, monochromatic near-infrared photoenergy; ADL, activities of daily living.

^aPatients over 64 years and had used ATS for at least 1 month; ^bMeans (SD).

Table 2. Outcomes in five groups of diabetic patients after MIRE™

| | Months of home access to MIRE™ after reversal of DPN | | | | |
|-----------------------|--|-----------|-----------|------------|------------|
| | 1–3 | 3–6 | 6–9 | 9–12 | 12+ |
| Number of patients | 36 | 33 | 22 | 94 | 67 |
| Months after MIRE™ | 1.2 (0.14) | 4.0 (0.8) | 6.7 (0.9) | 10.1 (0.7) | 13.3 (1.0) |
| Age | 75 [8] | 74 [7] | 76 [6] | 76 [7] | 76 [6] |
| Male/female | 23/14 | 20/13 | 9/13 | 44/50 | 40/27 |
| Number who fell (B) | 12 | 9 | 8 | 20 | 24 |
| Two or more falls (B) | 7/12 | 6/9 | 6/8 | 18/20 | 16/24 |
| Number who fell (A) | 2* | 4** | 7 | 9* | 11* |
| Decrease in falls (%) | 83 | 60 | 13 | 50 | 54 |
| Reduced falls (%) | 100 | 78 | 50 | 70 | 83 |
| Fear (B) | 26/36 | 21/33 | 16/22 | 57/94 | 46/67 |
| Fear (A) | 2/36* | 6/33 | 4/22 | 7/57 | 16/67 |
| Reduced fear (%) | 92 | 70 | 75 | 88 | 65 |
| ADL increase | 25/36* | 22/33* | 17/22* | 69/94* | 49/94* |
| ADL % (A) | 69 | 67 | 77 | 73 | 73 |
| Some increase (ADL) | 16/25 | 14/22 | 7/17 | 31/69 | 34/49 |
| Increase in ADL (%) | 64 | 64 | 41 | 45 | 69 |
| A lot more (ADL) | 9/25 | 8/22 | 10/17 | 38/69 | 15/49 |
| Increase in ADL (%) | 36 | 36 | 59 | 55 | 31 |
| Pain reduction (%) | 94* | 80* | 91* | 85* | 91* |

DPN, diabetic peripheral neuropathy; B, before MIRE™; A, after MIRE™; Fear, fear of falling and/or balance problems; ADL increase, those with increased activities of daily living (ADL) after MIRE™; Some increase, able to do somewhat more after reversal of DPN; A lot more, able to do much more after reversal of DPN; Pain reduction, percentage of patients who reported a reduced pain level (visual analogue scale) after reversal of DPN.

* $P < 0.0001$; ** $P < 0.01$.

(i) reduce the incidence of falls, (ii) reduce fear of falling and (iii) improve ADL in diabetic patients over 64 years.

A recent report [30] noted that the incidence of at least one fall in patients with DPN was 29%, the incidence of multiple falls was 21%, and most patients with DPN (66%) feared falling. The present data indicate that reversal of DPN is associated with dramatic reductions in both the frequency of reported falls (78%) and in the fear of falling (79%). Additionally, significant reductions in the frequency of reported falls and the fear of falling were apparent when patients had access to the ATS at home for 1–3 months after reversal of DPN; these reductions in falls remained evident up to 15 months after reversal of DPN. Although we know of no studies that report a reduction in falls, specifically in patients with DPN, it has been reported that a combination of group exercise, visual improvement strategies and home hazard reduction results in an estimated 14% reduction the annual fall rate [31]. Clearly, the 78% reduction in the number of falls in diabetic patients using the ATS, as documented in the present study, confirms earlier observations [23] and suggests the ATS may be an additional therapeutic intervention that may be of significant benefit in preventing falls among patients with DPN.

The prevalence of peripheral neuropathy of any aetiology in those aged 60–74 years (a somewhat younger cadre of seniors than those in the present study) has been estimated at 22% and it was suggested that this was likely to increase with age [5]. Moreover, the incidence of falls in this younger group was reported to be 50% [5]. Accordingly, the present data indicate that it may be possible to reduce this incidence of falls to approximately 10% in Medicare-aged seniors with peripheral neuropathy due to causes other than diabetes.

Richardson *et al.* [16] have reported that while exercise may reduce certain risk factors associated with falls in those with peripheral neuropathy, exercise itself has no significant effect in reducing the fear of falling. The data presented in this study suggest that restoring sensation may significantly reduce the fear of falling because 79% of the patients reported a diminished fear of falling. Because the fear of falling is an independent risk factor for a subsequent fall(s) within 20 months after a first fall [17, 18], our data suggest that it may be possible to reduce this risk factor.

The reduction in the fear of falling, and the decrease in neuropathic pain reported by 87% of all respondents, may have contributed to the 72% increase in activity level. One hundred and eighty-two patients reported an increased activity level and 80 (44%) reported being able to do much more on a daily basis after reversal of DPN. Increased activity among seniors, with or without diabetes, provides a wide range of net health benefits, economically, emotionally and physically. The present results suggest that reversing DPN and concomitantly reducing its associated pain may be expected to increase daily activity levels in those over 65 years of age, including those over 80 years of age, who showed similar improvements as the study group as a whole.

We acknowledge certain limitations in our study. For example, although reversal of DPN and decreases in neuropathic pain were objectively substantiated through analysis of written physician orders and supporting treatment notes, we relied solely on patient response to determine the incidence of falls, fear of falling and changes in ADL after reversal of DPN. Similar methodology is often used in studies related to falls [5, 31]. However, it is possible that

patients' recall may be inaccurate or incomplete, or that unintentional interviewer bias during telephone questioning may have occurred. The data presented in this article are further stratified by the duration between the initial treatment effect and the date the patient responded to the questionnaire. Intuitively, those responses that were offered very soon after the treatment would seem to be most reliable. However, those responses that were offered up to a year after treatment are not necessarily unreliable, particularly in relation to falls, which are major health-threatening events that are more likely to be remembered than more trivial matters. Despite these limitations, the answers of those interviewed 1–3 months after reversal of DPN were quite similar to those interviewed at 12–15 months. Because the data in each subgroup are remarkably similar, it would appear that the results, as a whole, are reliable. We also attempted to minimise interviewer bias by utilising eight separate interviewers in this study.

Certainly, use of randomised control groups is the ideal study design. However, when one is assessing potentially very dangerous health-care events such as falls in the elderly, it is very difficult to justify withholding available treatments or risk reduction strategies. Under these circumstances an observational approach using the patient as their own control seemed an appropriate analysis for these patients, subject of course to the limitations that are inherent in such designs. In so doing, these patients described meaningful patient-centred quality of life changes over time in response to active treatment and although glycaemic control is well known to delay microvascular complications of diabetes it will not reverse them.

Finally, the discretionary comments offered by patients at the conclusion of the interviews substantiated overall improvement in their condition. No multivariate analysis of known co-morbid risks for falls was undertaken and it is possible that some of the reported fall reductions resulted from other variables. However, recognised co-morbidities and medications associated with falls have been found not to be predictive of falls in patients with peripheral neuropathy [5]. We do agree with the widely held belief that the causes of falls are multifactorial and the best approach is a holistic one designed to reduce all applicable risk factors for the patient. Clearly, the literature recognises that peripheral neuropathy is one substantial independent risk factor for falls. In the context of this article, we investigated whether removing this one risk factor in a cohort of community-dwelling patients, who had previously exhibited this risk factor, would decrease the number of falls they reported over time. The data gathered support this salutary effect.

Conclusion

When diabetic patients have continuing access to MIRE™ in their homes following restoration of protective sensation, there is a significant reduction in the incidence of falls and fear of falling that is recognised as being closely associated with DPN. The increased activity in elderly diabetic patients may be related to improved balance and reduced pain

which, based on these data, can occur with use of MIRE™ in a clinic. Reversal of DPN may have major socioeconomic benefits including the potential for significant cost savings to the Medicare system and an improved quality of life for diabetic patients.

Key points

- Restoration of sensation in the lower extremity of diabetic patients over the age of 64 reduces their fear of falling and the number of falls generally associated with loss of sensation.
 - In addition, pain is diminished and quality of life is markedly improved.
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