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Sequential Contraction Compression Device Therapy affects Symptomatic Diabetic Peripheral Neuropathy

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Abstract

The authors evaluate a novel compression device, Sequential Contraction Compression Therapy Device (SCCD) on patients with hypo esthetic Diabetic Peripheral Neuropathy. The authors selected 15 patients all of whom had a diagnosis of DPN and were currently taking 150 mg. of Pregabalin twice daily. After thirty days of treatment with SCCD, patients were evaluated for improvement in their pain score, amount of rescue drugs used, and the amount of sleep interference they experienced. All patients experience statistically significant improvement in all three measurements.

Keywords: Diabetic peripheral neuropathy; Compression therapy; Diabetes; Muscle stimulation

Introduction

Diabetic Peripheral Neuropathy is a chronic, symmetrical, length-dependent sensorimotor polyneuropathy (DSPN) and is thought to be most commonly divided into hyperesthetic DPN and hypoesthetic DPN [1]. DPN develops from a background of long-standing hyperglycemia, associated metabolic derangements oxidative stress, and lipid alterations and cardiovascular risk factors [2,3]. A newer hypothesis for a contributing factor to DPN is the alteration of microvessels, similar to those observed in diabetic retinopathy and nephropathy, affecting the nerves [4,5].

It has been reported in the literature that between 3 and 25% of patients with DPN will have neuropathic pain [6]. The symptoms include distal, symmetrical, exacerbated nocturnally, and commonly described as prickling, deep aching, sharp, like an electric shock, and burning with hyperalgesia and frequently allodynia upon examination [7].

Pharmacological management of painful DPN almost exclusively consists of symptomatic therapies [8]. These drugs are often associated with side effects including somnolence, dizziness, nausea and compliance is mixed.

Sequential contraction compression device (SCCD) therapy has shown effectiveness in treating circulatory disorders of the lower extremities [9]. The method of action of the SCCD is to increase venous outflow from the limb by a series of peristaltic contractions of the calf muscles. The resultant change in the AV gradient causes an increased inflow to the limb [10].

The new understanding that DPN is also microvascular disease would predict an indication for treatment of DPN with circulatory enhancers. The authors evaluate a sequential contraction compression device (SCCD), the Flowaid FA-100 (Flowaid Medical Technology Corp. New York, USA) for the treatment of painful diabetic peripheral neuropathy.

Materials and Methods

15 patients were enrolled in the study. Table 1 demonstrates the demographic distribution of the study subjects.

Patient Number	Age	Gender	Duration of Condition (years)
1	64	M	1.5
2	57	F	4
3	63	F	3
4	68	M	1
5	72	M	7
6	54	M	5
7	56	F	4
8	67	M	3
9	62	M	3
10	70	F	4
11	69	M	3
12	58	F	4
13	49	M	4
14	57	M	5
15	47	F	5

Table 1: Demographic Data of Subjects

All 15 had a diagnosis, confirmed by Nerve Conduction Velocity (NCV) of Diabetic Peripheral Neuropathy that was not complicated by a more central lesion such as radiculopathy or nerve root inflammation. All 15 were symptomatic with pain, burning, and awakening at least almost every night for a minimum of 6 months. All 15 were currently taking Pregabalin 150 mg. bid for at least 30 days with no relief from their symptoms. All had also tried at a minimum at least one course of Cymbalta prior to being switched to Pregabalin.

Upon enrolment, subjects were asked to complete a questionnaire, which included a Visual Analog Scale (VAS) pain scoring, a record of how much rescue analgesics they were taking beyond the Pregabalin prescription in an average 24 hour period, and a record of how many times they were awakened from their sleep on the average night. Patients also underwent a baseline NCV.

Subjects were given a Flowaid FA-100 (Flowaid Medical Technologies Corp. New York, USA) Sequential Contraction Compression Device (SCCD) to use at home for two hours per leg once daily. The SCCD was set to the PA setting. Patients were monitored for compliance by daily phone calls from a study assistant.

After 30 days of treatment with the SCCD subjects returned for reevaluation and completed the same questionnaire they did at intake, as well as undergoing a follow up NCV.

The study was approved by an IRB before any patients were enrolled, and patients signed an informed consent at the beginning of the study procedure.

Results

Table 2 summarizes the results of the study. All patients showed a positive reaction to treatment with SCCD in all three measured parameters.

Patient Number	VAS Pre-Study	VAS at 30 days	Rescue Drug Usage Pre Study	Rescue Drug Usage at 30 days	Times Awakened Pre Study	Times Awakened at 30 Days
1	8	4	4	1	3	0
2	7	4	3	1	4	1
3	7	3	3	0	3	0
4	9	4	4	0	4	0
5	8	2	3	1	3	1
6	6	2	3	0	3	0
7	7	3	2	0	3	0
8	7	3	4	1	4	1
9	7	2	3	1	4	0
10	8	4	4	0	3	1
11	8	3	3	0	2	0
12	9	4	5	1	3	1
13	8	3	3	1	3	1
14	7	3	2	0	3	0
15	6	2	2	0	2	0

Table 2: Summary of the Results of the Study

Paired-samples t-tests were utilized to compare pre-drug treatment scores to post-treatment scores for three outcomes: VAS, rescue drug usage, and times awakened. The t-tests showed that there were significant improvements for each of the outcomes. The average VAS improvement was 4.4 (pre-treatment mean=7.5, post-treatment mean=3.1), $t(14)=23.1$, $p<.001$). The average rescue drug usage improvement was 2.7 (pre-treatment mean = 3.2, post-treatment mean=0.47), $t(14)=13.2$, $p<.001$). The average improvement in times awakened was 2.7 (pre-treatment mean=3.1, post-treatment mean=0.4), $t(14)=15$, $p<.001$).

12 of the 15 patients related significant improvement in the first week.

NCV studies showed a trending toward improvement but the results were not significant.

Discussion

While traditionally DPN was thought to be a metabolic disease, newer research shows that micro ischemia, and pathologic alterations of the micro vessels play an important role in the progression of the disease [1,11]. The authors have previous experience with the SCCD and have seen its effect on distal blood flow in the lower extremities [9,10]. The authors have also seen prior to this study anecdotal evidence of a positive effect of SCCD on symptomatic painful DPN.

Because this was the first study of SCCD for the treatment of painful DPN, it was kept to an open label observational study. While the limitations of such a study are known, the inclusion criteria were carefully monitored and based on the recommendations of the Diabetic Neuropathy Study group [12]. These included NP associated with DPN for >6 months duration, mean weekly pain score of between 4 and 10 on an 11-point numerical rating scale, exclusion of pain not associated with DPN, mononeuropathies or proximal neuropathies, non-neuropathic chronic pain, and central pain.

Evaluation of subjects was also done in line with recommendations of the Study group as well as based on the construct of previously published literature of other modalities for the treatment of DPN. The study group states that the severity of pain can be reliably assessed by the visual analog scale, which is the oldest and best validated measure, or the numerical rating scale, e.g., the 11-point Likert scale (0=no pain, 10=worst possible pain). They also state that external observers can play no part in the assessment of the subjects' responses to new therapies for NP; thus, measures such as the "physician's global impression of response" are not valid.

SCCD compared well with results reported for Pregabalin effect on neuropathic pain which ranged from 11%-13% [13,14]. It also compared well with regard to sleep interference [15,16].

Because SCCD is a mechanical modality and there is no drug usage, no drug- drug interacting or pharmacological side effects are observed.

The authors hypothesize that by hyperperfusing the limb, excess arterial pressure is shifted into the microvasculature where it is then able to regenerate hypoxic and ischemic nerve tissue.

Neuroregeneration would have an effect on objective examinations such as NCV, but it is expected that these results would lag, perhaps even significantly behind the subjective results.

This study was limited by the sample size which was small and did not lend itself to a full statistical evaluation of the subject's results. In addition, the duration of the observation lent itself to a good evaluation of subjective data but did not allow for objective results to occur. Lastly, the open label nature of the study, did not give a full picture of the efficacy of the study device. Only through an randomized controlled trial could these things be properly evaluated. Further research should include a larger sample size, with a sham or placebo controlled arm. It should follow subjects for longer to give enough time for NCV results to occur. Other tests such as nerve fiber density evaluation should also be considered.

Conclusion

SCCD shows effectiveness in treating painful DPN. While the results of this study were significant, a larger scale, randomized clinical trial is indicated. It is also suggested that any such trial document the progression of subjective results more frequently, follow for a longer time to evaluate for objective findings as well. The newer understanding of the micro ischemic nature of DPN and the results shown in studies such as this one could alter the way DPN is treated.

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