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A randomized controlled, single-blind trial to investigate if an electrical current – Non-Interventional Pulsed Radio Frequency (NI PRF) - could improve neuropathic pain and symptoms in patients with diabetic peripheral neuropathy

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Background: The prevalence of peripheral diabetic neuropathy (PDN) in diabetic patients is the most common complication of diabetes. This is due to a consequence of long established hyperglycaemia that alters the physiology of peripheral nerves and precipitates a metabolic cascade leading to peripheral nerve injury. Neuropathic pain is pain that arises as a direct consequence of a lesion or disease affecting the somatosensory system. PDN can be assessed by validated neuropathic pain questionnaires and in this study the Doleur Neuropathiqe 4 (DN4) Test and the Brief Pain Inventory Shortform (BPI-SF) were selected to evaluate pain intensity and quality of life. Clinically it has been observed that the neurostimulation device in question, NI PRF has relieved severe pain and improved nerve conduction in various conditions, including diabetic neuropathy and other neuropathic pain and symptoms.

Purpose: This randomized and controlled single blind trial intended to investigate changes in the DN4 Test and the BPI-SF in patients with DPN after three treatments of the NI PRF electrical current. These changes would be evaluated from baseline, 3 weeks after the last treatment and then followed up one month, three months and six months after the last treatment. Patients with both type 1 and type 2 diabetes would be included in the trial. The tools assessing these patients will indicate whether this treatment affects neuropathic pain and symptoms (DN4) and implements improvements in the BPI-SF of: visual analogue scale (VAS) of worst, least, average and present pain, medication use and percentage improvements, interfers with: general activities, mood, walking and work ability, relations with other people, sleep and quality of life.

Method: The patients were randomized into a treatment and non-treatment/placebo group. Each patient was given an assessment of DN4 to determine if they qualify as having neuropathic pain (NP) with a score of 4 and 4+/10. If the patients have qualified they then continue with the BPI-SF and treatment and or placebo can then proceed. Treatment or placebo is provided at the sciatic nerve above the bifurcation at the popliteal fossa for 10mins on each leg. Patients were then given 3 treatments once weekly and then follow up only of the DN4 and BPI-SF is given at 3 weeks, 1 month, 3 and 6 months after the third/last treatment. Patients are reimbursed for their travelling expenses after each attendance – for treatments or the assessments only. The data is analysed by an independent statistician (Libhaber E, University of the Witwatersrand). At present 46 patients in both groups have been processed and it is intended to evaluate 80 patients to complete this study.

Preliminary Results: Presently, patients at baseline are – 46 patients, 23 in the active group (A) and in the 23 in the placebo group (B). The p values indicate the differences between the active and the placebo groups.

DN4 Test

The DN4 Test indicates a significant change from baseline to:

Post 3rd treatment – p value 0.011 (A = 22, B = 23)

These changes were maintained at:

1month follow-up – p value 0.047 (A = 20, B = 21)

6month follow up – p value 0.013 (A = 16, B = 12)

The VAS scores demonstrated significance at 1month for:

Present pain p = 0.018

Average pain p = 0.043

Worst pain p = 0.002

There was also significance at 6months in:

Mood p = 0.041 (A = 16, B = 12)

However at 3months no significance was demonstrated in the p values but this may have been due to confounding factors as one patient (A) had increased nociceptive pain (plantar fasciitis) that may affect neuropathic pain levels, another patient (B) having discrepancy between minimal neuropathic pain in the DN4 and yet severe pain in the VAS, another patient (B) requiring increased medication for night pain and finally a reduced number of patients in the 3month group with A = 19, B = 15.

There were no significant changes in medication use, interference with work and walking ability at 3weeks, 1,3 and 6months and it may be postulated that greater numbers of patients may yet demonstrate significance.

Conclusion: The preliminary results above indicate positive trends in neuropathic pain and symptoms after 3 treatments. This is consistent with clinical observations after 3 treatments with NI PRF electrical current in both neuropathic and nociceptive pain conditions from different aetiologies. The most significant changes occur at 1month in 'worst' pain – clinically this is usually evident after 3 treatments with the NI-PRF from any aetiology. The significance at 6months in mood is heartening as it indicates that the placebo effect had waned and the positive effects of treatment were still evident and it has also been notable that in other conditions treated with NI-PRF once pain has diminished other symptoms improve and full restoration of function often occurs.

Biography

She is a physiotherapist and acupuncturist. She qualified at the University of the Witwatersrand, Johannesburg, South Africa in 1966 and as her experience grew in orthopaedics and neurology, She developed a special interest in the treatment of chronic pain. This has led her to participate in various international organisations that specialise in the study and research of pain management. Her own experience of treating many chronic and intractable pain patients made me realise that often medication and interventions, including surgery does not always solve the problems.

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