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Homoeopathic treatment on diabetic distal symmetric polyneuropathy [ddsp]: a systematic review.

Tratamiento homeopático de la polineuropatía diabética distal simétrica [ddsp]: una revisión sistemática.

Dr.Simran Samdani[*] , Dr. Sameer S. Nadgauda [#]

*Post Graduate Scholar, Department of Practice of Medicine, Bharati Vidyapeeth (Deemed to be University),Homoeopathic Medical College and Hospital, Pune Satara Road,India – 411043.

Email: samdanisimran@gmail.com

Assistant Professor, Department of Practice of Medicine, Bharati Vidyapeeth (Deemed to be University),Homoeopathic Medical College and Hospital, Pune Satara Road,India – 411043.

Email:sameer.nadgauda@bharatividyapeeth.edu

Author for Correspondence:

Dr. Sameer S. Nadgauda, Assistant Professor, Department of Practice of Medicine, Bharati Vidyapeeth (Deemed to be University),Homoeopathic Medical College and Hospital, Pune Satara Road,India – 411043.

Email:sameer.nadgauda@bharatividyapeeth.edu

ABSTRACT

Background: An epidemic of the disorders/ complications is paralleling the global epidemics of prediabetes and diabetes. The most frequent complication is neuropathy, of which distal symmetric polyneuropathy (DDSP) is very common. Diabetic neuropathy is characterised by pain and significant morbidity, as well as a loss of sensory function that begins distantly in the lower extremities. At least 50% of people with diabetes eventually develop diabetic neuropathy. In patients with type 1 diabetes mellitus, glucose control effectively slows the progression of diabetic neuropathy; however, the effects are less pronounced in patients with type 2 diabetes mellitus. Material and Methods: To locate clinical research publications, a computerised literature search was conducted. A thorough search of PubMed, Medline, Google Scholar, ScienceDirect, and the Thieme-E-journal of homoeopathy was done. This review only included clinical studies that involved humans. Pilot research, animal experiments were excluded. All prospective observational clinical research studies that were randomised, double-blind, and placebo-controlled were included. Conclusion: This systematic review concluded that homeopathic medicines are safe and effective in management of Diabetic Distal Symmetric Polyneuropathy (DDSP). But more randomized placebo controlled studies should be conducted to strengthen the available evidence.

Keywords: Homeopathy, diabetic neuropathy, DDSP, peripheral neuropathy, randomized clinical trials in diabetic neuropathy and homeopathy.

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RESUMEN

Antecedentes: Una epidemia de trastornos/complicaciones es paralela a las epidemias globales de prediabetes y diabetes. La complicación más frecuente es la neuropatía, de la cual la polineuropatía simétrica distal (DDSP) es muy común. La neuropatía diabética se caracteriza por dolor y morbilidad significativa, así como por una pérdida de la función sensorial que comienza a distancia en las extremidades inferiores. Al menos el 50% de las personas con diabetes acaban desarrollando neuropatía diabética. En pacientes con diabetes mellitus tipo 1, el control de la glucosa retarda eficazmente la progresión de la neuropatía diabética; sin embargo, los efectos son menos pronunciados en pacientes con diabetes mellitus tipo 2. Material y Métodos: Para localizar publicaciones de investigación clínica, se realizó una búsqueda bibliográfica computarizada. Se realizó una búsqueda exhaustiva en PubMed, Medline, Google Scholar, ScienceDirect y Thieme-E-journal of homeopathy. Esta revisión solo incluyó estudios clínicos en humanos. Se excluyeron las investigaciones piloto y los experimentos con animales. Se incluyeron todos los estudios de investigación clínica observacionales prospectivos que fueron aleatorios, doble ciego y controlados con placebo. Conclusión: Esta revisión sistemática concluyó que los medicamentos homeopáticos son seguros y eficaces en el tratamiento de la polineuropatía simétrica distal diabética (DDSP). Pero se deben realizar más estudios aleatorios controlados con placebo para fortalecer la evidencia disponible.

Palabras clave: Homeopatía, neuropatía diabética, DDSP, neuropatía periférica, ensayos clínicos aleatorizados en neuropatía diabética y homeopatía.

INTRODUCTION

Diabetic neuropathy is defined as the presence of symptoms and/or signs of peripheral nerve dysfunction in a patient with diabetes, after the exclusion of other causes. In course of diabetes, some 20-90% of individuals eventually develop diabetic neuropathy. Diabetes affects approximately 246 million people worldwide out after and of these about 20-30 million people worldwide are affected by symptomatic diabetic neuropathy.[1] Prevalence of peripheral neuropathy in diabetic patients ranges from around 10.5% to 32.2% in various studies across India. More than 80% of patients with clinical diabetic neuropathy have a distal symmetrical form of the disorder.Blood sugar levels and duration of the disease are the main risk factors for development of this disease. So, it is essential to develop a strategy to stop the progression of this disabling condition to the extent possible. The conventional treatment includes non-steroidal anti-inflammatory drugs (NSAIDs), anti-depressants, etc., which are having side effects and are even contraindicated in certain conditions.There are no specific guidelines for painful diabetic neuropathy and many patients remain untreated or undertreated.[1]

Stages of diabetic peripheral neuropathy[2]

Stage of diabetic peripheral neuropathy	Characteristics
Stages 0/1: no clinical neuropathy	
	No symptoms or signs
Stage 2: clinical neuropathy	
Chronic painful	Positive symptomatology (increasing pain at night): burning, shooting, stabbing pains ± pins and needles
	Absent sensation to several modalities and reduced or absent reflexes
Acute painful	Less common
	Diabetes poorly controlled, weight loss
	Diffuse (trunk)
	Hyperaesthesia may occur
	May be associated with initiation of glycaemic therapy
	Minor sensory signs or even normal peripheral neurological examination
Painless with complete/partial sensory loss	No symptoms or numbness/deadness of feet; reduced thermal sensitivity; painless injury
	Signs of reduced or absent sensation with absent reflexes
Diabetic amyotrophy	Muscle weakness and wasting
	Sensory loss is slight, but pain at night common

Subacute onset

Stage 3: late complications of clinical neuropathy

Foot lesions, e.g. ulcers

Neuropathic deformity, e.g. Charcot joint

Non-traumatic amputation

TREATMENT

Prevention of diabetic neuropathy is critical through improved glycemic control[2].Lifestyle modifications (exercise, diet) has some efficacy in DSPN in type 2 DM and hypertension and hypertriglyceridemia should be treated.Avoidance of neurotoxins (alcohol) and smoking, supplementation with vitamins for possible deficiencies (B12, folate). Patients should be educated that loss of sensation in the foot increases the risk for ulceration and its sequelae and that prevention of such problems is paramount. Patients with symptoms or signs of neuropathy should check their feet daily and take precautions (footwear) aimed at preventing calluses or ulcerations. If foot deformities are present, a podiatrist should be involved. Two agents, duloxetine and pregabalin, have been approved by the U.S. Food and Drug Administration (FDA) for pain associated with diabetic neuropathy.[3]Diabetic neuropathy may respond to tricyclic antidepressants, gabapentin, venlafaxine, carbamazepine, tramadol, and topical capsaicin, although none of these are FDA-approved for this indication.[2]The pain of acute diabetic neuropathy may resolve over time, medications may be discontinued as progressive neuronal damage from DM occurs.[3]Nonpharmacologic maneuvers (adequate salt intake, avoidance of dehydration and diuretics, and lower extremity support hose) may offer some benefit. [3]

HOMOEOPATHIC MANAGEMENT

LYCOPODIUM CLAVATUM

BY DR W. BOERICKE-

Numbness, also drawing and tearing in limbs, especially while at rest or at night. Heaviness of arms. Tearing in shoulder and elbow joints. One foot hot, the other cold. Chronic gout, with chalky deposits in joints. Profuse sweat of the feet. Pain in heel on treading as from a pebble. Painful callosities on soles; toes and fingers contracted. *Sciatica, worse right side. Cannot lie on painful side*. Hands and feet numb. Right foot hot, left cold. Cramps in calves and toes at night in bed. Limbs go to sleep. Twitching and jerking.[4]

BY DR J .H. CLARKE

Tearing in legs and knees, extending to tibia and instep,Cramps and cramp-like pains in the calves, esp. when walking, and at night.–Burning pain in legs.Ulcers in the legs, with nocturnal tearing, itching, and burning heat.[5]

METHODOLOGY

A thorough computerised literature search was conducted to locate clinical research publications. Searches were conducted on relevant papers in PubMed, Cochrane, Wiley, Google Scholar, Research Gate, Medline, Science Direct, and the Thieme-E-journal of Homoeopathy. This review only included clinical studies that involved humans. Pilot research, animal experiments were excluded. Case series detailing a sufficient number of cases (more than 20) and controlled clinical trials (randomized or non-randomised) were also acceptable for inclusion. All prospective observational clinical research studies that were randomized, double-blind, and placebo-controlled were included. Additionally, we did not include any papers that did not apply to our research ,articles and opinion pieces lacking a conclusive statement were removed.

DISCUSSION

A clinical observational study conducted by CCRH on patients with diabetes mellitus (DM) who had diabetic polyneuropathy symptoms came to the conclusion that there had been a statistically significant improvement in DDSPSS total score at 12 months following baseline ($p = 0.0001$). The majority of objective metrics did not significantly improve. The most commonly prescribed drugs were Lycopodium clavatum (n=132), Phosphorus (n=27), and Sulphur (n=26). According to a study, homoeopathic medications may be useful in treating DPN patients' symptoms.[6]

Another prospective observational study used homoeopathy in one group while simultaneously observing the effects of conventional therapy. During the observation period, DNS improved in both groups, but only the homoeopathic group's change from baseline was statistically significant. While the electroneuromyophysiological parameters, blood pressure, and body weight were significantly stable in both groups, the homoeopathic group had a small decline in fasting blood sugar levels and glycated haemoglobin. Only the homoeopathic group's QOL scores improved.[7]

Another study offers data to support the claim that providing homoeopathic medicines significantly reduces the disease intensity scores. This implies that homoeopathic drugs have a very important role in the management of DDPN. Vibration Perception Threshold (VPT) reduction is another benefit of it. Using a biothesiometer, the VPT of the foot was quantitatively quantified both before and after therapy. The pre- and post-test assessment integrated the benefits of DNE Scoring and the symptom scoring chart. The outcomes have statistical significance. Sulphur and Lycopodium are two medications that have been found to be more effective.[8]

15 homoeopathic remedies were shortlisted for a double-blind, placebo-controlled, randomised clinical trial that was carried out. Validated measures were also employed.The World Health Organization Quality of Life BREF (WHOQOL-BREF), the Diabetic Neuropathy Examination (DNE) Score, changes in peripheral nerve conduction study (NCS), and the Neuropathy Total Symptom Score-6 (NTSS-6) were all taken into consideration during the trial. The approach did not prove that homoeopathic drugs were clearly superior as a supplement to conventional treatment.

To evaluate the efficacy of homoeopathic medications in the treatment of diabetic polyneuropathy, additional research must be conducted with a bigger sample size and defined conditions for nerve conduction investigation.[9]

An analysis of the open clinical observational study were assessed using symptoms and signs assessment score (SSAS). 15 pre-determined medications in the potencies of 30, 200, and 1M on the centesimal scale were prescribed. Electrodiagnostic function, blood pressure, body weight, fasting and post-prandial blood sugar, HbA1C, and microalbumin in urine all significantly decreased. Lycopodium, Sulphur, and Phosphorus were prescribed in 30, 200, and 1M potencies. [10]

Recombinant human nerve growth factor (rhNGF) was tested in a phase 3 randomised, double-blind, placebo-controlled experiment for the treatment of peripheral neuropathy. Injection site discomfort/hyperalgesia and other pain syndromes were the only side effects associated with the safe administration of rhNGF.This phase 3 clinical trial was unable to show that rhNGF significantly improved diabetic polyneuropathy.[12]

Another study to assess the effects of aldose reductase inhibitors on the progression of symptoms, signs or functional disability in diabetic polyneuropathy.When treating diabetic polyneuropathy, there was no statistically significant difference between aldose reductase inhibitors and a placebo. Aldose reductase inhibitors should only be studied in human clinical trials if they have been shown to offer significant biological or preclinical advantages over currently approved medications. [13]

A research project to evaluate the effects of the DPN medication acetyl-L-carnitine (ALC)was done. Given the lack of data and poor certainty, it is unclear whether ALC, when compared to a placebo, reduces pain in DPN patients after 6 to 12 months of treatment. There are relatively few or uncertain data on functional and sensory impairment and symptoms. To reach any conclusions about safety based on the data of adverse events would be premature. [14]

In order to determine the impact of ruboxistaurin (RBX) mesylate on nerve function and sensory complaints in patients with diabetes mellitus (DM) and diabetic peripheral neuropathy, a global, randomized, Phase II, double-blind, parallel-group experiment was conducted. (DPN).DPN was discovered through abnormal neurologic testing and confirmed by abnormal vibration detection threshold (VDT) measurements.The DPN patients who took part in this trial seemed to tolerate RBX well. Overall, there was no difference between treatment groups at the end point in changes to the VDT and NTSS-6 total scores. The subgroup of patients with less severe symptomatic DPN, however, appeared to benefit from RBX treatment because it reduced sensory complaints and enhanced nerve fibre function, as seen by declines in VDT and NTSS-6 total score. [15]

RESULT

There are no treatments for neuropathy other than treating the diabetic condition per se. Other risk factor reductions for DPN have not yet been the subject of conclusively beneficial preventative research, but it is already advised against smoking, drinking excessively, and having high blood pressure.[16]Anticonvulsants and antidepressants are still the most commonly used options to manage diabetic neuropathy. Oral tricyclic

antidepressants and traditional anticonvulsants are better for short term pain relief than newer generation anticonvulsants.[3,16] Since hyperglycemia is a modifiable risk factor for diabetic neuropathy, intensive glycemic control is the most effective established therapy for reducing the incidence or slowing the progression of neuropathy and improving quality of life in diabetic patients. [17]

Several clinical trials have already failed to show improvement of diabetic neuropathy in patients with type 1 and 2 diabetes [16,18] For example, there is no therapeutic benefit of acetyl-carnitine, aldose reductase inhibitors, or NGF in human diabetic neuropathy [12,13,14]. What is required is combination therapy. [18]Homoeopathy has given promising results in management of DPN. But more randomized placebo controlled studies should be conducted to strengthen the available evidence.

Conflict of Interests (if any): There are no conflict of interests.

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Table – 1 Trials done for DDSP in Homoeopathy

S.N	Author's & Year	Intervention	No. of subject	Conditioned studied	Study Type	Key Results
1.	Chaturbhuja Nayak and et al 2013	15 predefined homoeopathic remedies	247	Diabetic polyneuropathy (DPN)	Clinical observational study	Patients were evaluated by the Diabetic Distal Symmetric Polyneuropathy Symptom Score (DDSPSS) developed by the Council *Lycopodiumclavatum* (*n* = 132), *Phosphorus* (*n* = 27) and *Sulphur* (*n* = 26) were the medicines most frequently prescribed. This study suggests homeopathic medicines may be effective in managing the symptoms of DPN patients.
2.	Raffaella Pomposelli et al 2008	conventional therapy and Homeopathy	conventional therapy 29 and Homeopathy 32	diabetic neuropathy	prospective observational study	A slight decrease of fasting blood glucose and glycatedhaemoglobin in Homeopathic group. QOL scores showed an improvement in Homeopathic group only Complementary homeopathic therapy of diabetic neuropathy was feasible and promising effects in symptom scores and cost savings were observed

3.	Sundara Pandiya Raj, S 2018	Homoeopathic treatment	30	DISTAL DIABETIC PERIPHERAL NEUROPATHY (DDPN	Clinical study	Vibration Perception Threshold (VPT) of foot is measured quantitatively by using biothesiometer and values of DNE Scoring were assessed before and after treatment. The medicines, which are found to be more effective are SULPHUR and LYCOPODIUM. This study provides an evidence to show that there is significant reduction in the disease intensity scores after administering Homoeopathic Medicines. Hence, we can infer that Homoeopathic medicines have a very predominant role in the treatment of DDPN.
4.	Pritha Mehra , Bindu Sharma ,et al 2021	Individualized homeopathic medicines	84	DDSP	Multi-centric double-blind, placebo controlled, randomised clinical trial	Positive trend was noted for Verum group as per the graph plotted for DNE score and assessment done for NCS.
5.	Dr. Hafeezullah BaigApril 11, 2012	15 pre-defined homoeopathic medicine	95	DDSP	Observational study	Outcome assessment of 83 patients showed improvement in varying degrees viz markedly improved in 25 (26.31%), moderately in 46 (48.42%) and mild in 12 (12.13%). Lycopodium, Sulphur and Phosphorus are frequently

						indicated and were prescribed in 30, 200 and 1M potencies.
6.	Raj Kumar Manchanda, and et al March 2019	15 predefined homoeopathic remedies	42	Diabetic Distal Symmetric Polyneuropathy (DDSP)	A double blind randomised placebo controlled clinical trial	Trial till under recruitement.

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