

ORIGINAL PAPER

A prospective multi-centric open clinical trial of homeopathy in diabetic distal symmetric polyneuropathy

Chaturbhuja Nayak¹, Praveen Oberai^{1,*}, Roja Varanasi¹, Hafeezullah Baig², Raveender Ch³, GRC Reddy⁴, Pratima Devi⁵, Bhubaneshwari S⁶, Vikram Singh¹, VP Singh¹, Hari Singh¹ and Shashi Shekhar Shitanshu¹

¹Central Council for Research in Homeopathy, New Delhi, India

²Drug Standardisation Unit (Homeopathy), Hyderabad, India

³Regional Research Institute (Homeopathy), Gudivada, India

⁴Clinical Research Unit (Homeopathy), Tirupati, India

⁵Regional Research Institute (Homeopathy), Guwahati, India

⁶Clinical Research Unit (Homeopathy), Puducherry, India

Objectives: To evaluate homeopathic treatment in the management of diabetic distal symmetric polyneuropathy.

Methods: A prospective multi-centric clinical observational study was carried out from October 2005 to September 2009 by Central Council for Research in Homeopathy (CCRH) (India) at its five Institutes/Units. Patients suffering from diabetes mellitus (DM) and presenting with symptoms of diabetic polyneuropathy (DPN) were screened, investigated and were enrolled in the study after fulfilling the inclusion and exclusion criteria. Patients were evaluated by the Diabetic Distal Symmetric Polyneuropathy Symptom Score (DDSPSS) developed by the Council. A total of 15 homeopathic medicines were identified after repertorizing the nosological symptoms and signs of the disease. The appropriate constitutional medicine was selected and prescribed in 30, 200 and 1 M potency on an individualized basis. Patients were followed up regularly for 12 months.

Results: Out of 336 patients (167 males and 169 females) enrolled in the study, 247 patients (123 males and 124 females) were analyzed. All patients who attended at least three follow-up appointments and baseline curve conduction studies were included in the analysis. A statistically significant improvement in DDSPSS total score ($p = 0.0001$) was found at 12 months from baseline. Most objective measures did not show significant improvement. *Lycopodium clavatum* ($n = 132$), *Phosphorus* ($n = 27$) and *Sulphur* ($n = 26$) were the medicines most frequently prescribed. Adverse event of hypoglycaemia was observed in one patient only.

Conclusion: This study suggests homeopathic medicines may be effective in managing the symptoms of DPN patients. Further studies should be controlled and include the Quality of life (QOL) assessment. *Homeopathy* (2013) 102, 130–138.

Keywords: Diabetes; Diabetic neuropathy; Homeopathy; Observational study; *Lycopodium clavatum*; *Phosphorus*; *Sulphur*

*Correspondence. Praveen Oberai, Central Council for Research in Homeopathy, 61-65, Institutional Area, Opposite D Block, Janakpuri, New Delhi 110058, India.

E-mail: oberai.praveen@gmail.com

Received 28 September 2010; revised 24 January 2013; accepted 5 February 2013

Introduction

The increasing prevalence of diabetes mellitus (DM) in recent years is attributed to various factors including ageing, urbanization, unhealthy diets, obesity and sedentary lifestyles. According to World Health Organization (WHO), there are about 143 million sufferers worldwide and this number is projected to rise to almost 300 million by 2025.¹ The International Diabetes Federation (IDF) also reports that number of diabetes patients in India was 41 million in 2006 and this would rise to 70 million by 2025.² Most diabetic patients have type 2 diabetes and almost all are at risk of developing complications.³

Complications of diabetes are of three categories.³ Firstly, metabolic complications particularly hyperglycaemia, hypoglycaemia and diabetic coma, secondly, macro-vascular complications, damage to the larger arteries leading to cerebro-vascular accidents, coronary heart disease and peripheral vascular disease and lastly micro-vascular complications leading to retinopathy, nephropathy and neuropathy.

Diabetic polyneuropathy (DPN) occurs in about 50% of individuals with long-standing type 1 and type 2 diabetes and may manifest as mononeuropathy, polyneuropathy and/or autonomic neuropathy. Among the polyneuropathies, distal symmetrical polyneuropathy (DSP) is the most common form. A number of modifiable and non-modifiable risk factors such as the degree of hyperglycaemia, duration of diabetes, lipid profile and blood pressure indices have been associated with DPN. Patients generally present with distal sensory loss but up to 50% are asymptomatic. Hyperaesthesia, paraesthesia and anaesthesia may also occur as neuropathy progresses.⁴ Physical examination reveals sensory loss, loss of ankle reflexes and abnormal position sense.⁵

Reports have suggested that diabetic neuropathy is not effectively controlled by conventional drugs even in patients with fair glycaemic control.⁴ Homeopathy is one of the commonly used complementary and alternative medicines (CAM) for DM and its complications.^{6,7}

The Central Council for Research in Homeopathy (CCRH), the premier homeopathic research organization in India has conducted several studies⁸⁻¹⁶ on the management of diabetes and its complications with homeopathic medicines. Medicines which may improve glycaemic control have been identified but in observational studies without specific assessment criteria. Some of these studies¹⁴⁻¹⁶ have used disease specific medicines like *Cephalandra indica*, *Rhus aromaticus*, *Ceanothus*, etc. Considering the outcome of these studies and ever increasing burden of DM and its complications in a developing country like India, the Council initiated an multi-centric observational study to evaluate individualized homeopathic treatment in the management of diabetic distal symmetric.

Objectives

Primary objective: To evaluate the potential role of homeopathic medicines in the management of diabetic neuropathy (DPN).

Secondary objectives: To verify characteristic symptoms of medicine(s) prescribed, to check the progression of disease and to consider the clinical findings like control of blood sugar levels, changes in symptoms and signs of peripheral neuropathy and changes in symptoms and signs of occlusive arterial disease.

Material and methods

Setting and design

A multi-centric observational study with 12 months follow up was conducted by CCRH at its five centres: Regional Research Institutes, Homeopathy (RRI) at Guwahati and Gudivada, Clinical Research Units, Homeopathy (CRU) at Tirupathi and Puducherry and Drug Standardization Unit, Homeopathy at Hyderabad between October 2005 to September 2009. Homeopathic physicians at these centres along with diabetologists at each centre directly interviewed the patients and prescribed medicines.

The study protocol was in accordance with the Helsinki¹⁷ declaration on human experimentation and Good Clinical Practices for Clinical Research in India.¹⁸ Ethical clearance was obtained from Council's Ethical Committee and the protocol was approved by the Scientific Advisory Committee of the CCRH. The study was funded by CCRH, Department of Ayurveda, Yoga, Unani, Sidha and Homeopathy (AYUSH), Ministry of Health and Family Welfare, Government of India. All the treating physicians were registered homeopathic practitioners and had more than 10 years of clinical experience. Training on the protocol was given to all the investigators prior to initiation of the study.

Participants

Diagnosed polyneuropathy patients (type I/type II) with DM attending general out patients' departments OPD(s) of the Institute and Units above the age of 30 years and presenting with symptoms and signs of DPN were enrolled in the study. Patients on conventional medication for diabetes prior to enrolment continued with them, the dose of such medication was monitored in consultation with the diabetologist during the follow-up period. Written informed consent was obtained from all the patients enrolled in this study.

Inclusion criteria:

- Age over 30 years with diagnosed type 1 or type 2 DM
- HbA1c, less than 8%
- Sensory loss
- Diabetic Distal Symmetric Polyneuropathy Symptom Score (DDSPSS) ≥ 3
- Written informed consent
- Patient meets prescribing criteria for one of the 15 preselected homeopathic medicines

Exclusion criteria:

- Diabetic mononeuropathy
- Polyradiculopathy
- Diabetic amyotrophy
- Autonomic neuropathy

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