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"A CLINICAL STUDY TO EVALUATE THE EFFECT OF AYURVEDIC FORMULATION IN DIABETIC NEUROPATHY"

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ABSTRACT

Diabetic Neuropathy is one of the most devastating complications of diabetes mellitus because of the debilitating symptoms it causes or associated higher risk of other complications. Even today, in the advanced world of Modern medicine, the pathogenesis and epidemiology of Diabetic Neuropathy is not yet completely known. This incomplete knowledge about pathogenesis and hence treatment of diabetic neuropathy invites an approach from other medical sciences like Ayurveda to explore its resources and provide a safe and promising treatment with least side effects. This research focuses on injury pathways in diabetic neuropathy which will be briefly summarized, an Ayurvedic approach to the etiology, pathogenesis and accordingly treatment modalities will be outlined based on the clinicaltrial conducted by the scholar.

KEYWORDS: Diabetic Neuropathy, Diabetes Mellitus.

INTRODUCTION

Diabetes Mellitus which is known to mankind since antiquity is a global attractive health problem of clinical medicine as it is growing in full pace, and alarming the world as a non infectious pandemic. Although by definition diabetes is characterised by elevated blood glucose concentration, the impact of diabetes on both the health of individuals and on health care system resides almost entirely in long term complication of diabetes. People with diabetes are 25 times more likely to develop blindness, 17 times more likely to develop

kidney disease, 30 to 40 times more likely to undergo a major amputation.[1] Diabetes mellitus has been correctly called as silent killer as it affects almost every system of the body and diabetic neuropathy is one of the commonest late complication of diabetes and concomittently one of the most distressing. Diabetic neuropathies are neuropathic disorders that are associated with diabetes mellitus. These conditions are thought to result from diabetic microvascular injury involving small blood vessels that supply nerves (vasa nervorum). Relatively common conditions which may be associated with diabetic neuropathy include third nerve palsy, mononeuropathy; mononeuropathy multiplex; diabetic amyotrophy; a painful polyneuropathy; autonomic neuropathy; and thoracoabdominal neuropathy. It is estimated that the prevalence of neuropathy in diabetes patients is approximately 20%. Diabetic neuropathy is implicated in 50-75% of nontraumatic amputations.[2]

As many as 60-90% of patients with diabetes suffer from peripheral neuropathy.[3] The various pathways leading to Nerve injury in diabetic patients are - Micro vascular changes, Pylol pathway, Oxidative stress, Nerve cell osmolyte disturbance, Altered Regulation of Na+-K+[4], Genetic Factors.[5] However, modern medicine does not have any truly effective treatment for this condition. In this pursuit, it has always been felt useful to explore the Ayurvedic resources. Ayurveda is a rich treasure of safe materia medica which provides a promising field of drug research, especially in view of least side effects of these herbal drugs. Keeping in view the non availability of a good and acceptable treatment for diabetic neuropathy and factual some untoward effects of existing modern drugs an attempt has been made to evaluate the effect of hydroalcoholic extract of *Dashmoola, Puskarmoola* and *Shuddha Hingu* powder in capsule form along with external application of *Masha Taila*. In the present clinical trial 23 patients of diabetic neuropathy were selected on subjective and objective criterias .The duration of trial was 45 days with regular follow up every 15 days. Effect of the therapy was assessed in total 22 patients (who completed the trial) on the basis of improvement in cardinal signs, symptoms and diagnostic criteria. The statistical analysis was done and results were found to be highly significant .The therapy is effective in Diabetic Neuropathy.

AIMS AND OBJECTIVES

- To evaluate the efficacy of trial drug containing hydroalcoholic extract of *Dashmoola, Puskarmoola* and *Shuddha Hingu* powder in capsule form along with external application of *Masha Taila* in the management of Diabetic Neuropathy.

- To study the adverse effect of the trial drug if any.

Plan of Study

To meet the above objectives, the research was planned under two headings.

1. Conceptual Study

Scattered references in Ayurvedic classics and modern literature pertaining to Diabetes and Diabetic Neuropathy were collected and put together for better understanding of the subject.

2. Clinical Study

This was main study of research work. The present clinical research work was carried out in associated hospital of R.G.G.P.G. Ayu. College, Paprola Distt. Kangra. Permission was taken duly from Institutional Ethical Committee before starting the clinical trial.

PATIENT AND METHODS

Selection of Patients

Total 23 Patients were selected from OPD and IPD of *Kayachikitsa* Deptt. of Rajiv Gandhi Govt. P.G. Ayurvedic. College Paprola, Distt. Kangra, H.P. fulfilling the criteria irrespective of their age, sex, religion etc. Patients were selected between age group 20-70yrs. Routine, blood examinations were carried out in order to rule out other pathology or to monitor the normal values of blood.

Diagnosis of Patients

Neuropathy signs were assessed with the help of Neuropathy kit-containing Buck reflex hammer to elicit deep tendon jerks, sterilized needle to check for pin sensitiviity, tip therm to check for perception of cold sensation, test tube for adding hot water to check for perception of hot sensation and a vibration tuning fork of 128Hz to assess the vibration perception of the patients.

Inclusion Criteria

1. Patients who are already diagnosed as Diabetics.
2. Patients whose blood sugar level >120mg/dl for more than 3 weeks.
3. Patients with symptoms of peripheral neuropathy such as Tingling sensation, Burning Sensation, Numbness, Pain.

Exclusion Criteria

1. Patients not willing for the trial.
2. Patients having neuropathy due to other disorders.
3. Diabetic patients associated with renal failure or any other terminal illness.

Investigations

Blood for Hb gm%, TLC, DLC, ESR, FBS, P.P.B.S., Blood Urea, Serum Creatinine, Glucose Tolerance test (GTT).

Protocol of Research

Consent

Written and informed consent of patients was taken before inclusion in the trial.

History Proforma

A special case history proforma was prepared. All the signs and symptoms and examinations and assessment were depicted in this proforma before inclusion and after completion of the study.

Patients Groups

All diagnosed patients who fulfilled the inclusion criteria were studied under one group.

Ingredients of Trial drug

The trial drugs consisted of two formulations an oral drug in capsule form and an oil for external

Application as Abhyanga

1. *Dashmoola (Bilva, Gambhari, Patala, Agnimantha, Shyonaka, Brihati, Laghu Kantkari, Shalparni, Prishnparni,Gokshru),* and *Pushkarmool* along with *shuddha Hingu*.[6]
2. *Mash tail* for *Abhyanga containing kwatha of mash, saindha lavana, tiltaila.*[7]

Preparation of Drug

1. The different ingredients of trial drug were got identified by *Dravya Guna* Deptt. Then the hydroalcoholic extract of *Dashmool* and *Pushkarmool* and Powdered *Shudha Hingu* was prepared in capsule from Ayush Herbs Pvt. Ltd. Nagrota Bhagwan which is a reputed Pharmacy under GMP license.

2. *Mash Taila* for local application (*abhyanga*) was prepared by adding *Mash* decoction and *saindhava lavana* in *Murchita til taila* at associated pharmacy of R.G.Govt. P.G.Ayu. College Paprola Distt. Kangra, H.P.

Administration and Dose of Drug

Oral Formulation

Each capsule (wt-575mg) containing
- 500mg *Dashmool* extract
- 50mg *Pushkarmool* extract
- 25mg *Hingu*

Dose - One capsule twice a day.

External Formulation as Abhyanga

Patients were properly educated to do *abhyanga* with *Mash Taila* twice a day with optimum pressure.

Duration of trial - 6 weeks.

Criteria for Assessment

Assessment was done on the basis of relief in symptoms and scoring system was adopted to assess the subjective signs and symptoms whereas objective parameters were assessed as per relief reported.

Gradation of various symptoms and signs in this clinical study

1. Karpada Daha

No burning sensation	G_0
Noticed but tolerable	G_1
Quite noticeable, does not affect routine sleep	G_2
Severe, whole day disturbs sleep and routine work	G_3

2. Tingling Sensation

No tingling sensation	G_0
Intermittent tingling sensation in upper & lower extremities in peripheries only	G_1
Continuous tingling sensation in upper and lower extremity extending whole length of extremities	G_2

Severe demanding attention all throughout day	G_3

3. Numbness

No Numbness	G_0
Mild Numbness in hands and feet	G_1
Moderate Numbness and Interferes perception	G^2
Severe Numbness with Low touch perception	G_3

4. Pain/Shoola

No Pain	G_0
Hyperesthesia	G_1
Resting pain with no medical requirement	G_2
Pain requiring medical intervention	G_3

5. Gloves and Stockings

No	G_0
Yes	G^1

6. Thermal Perception

Normal sensation to cold and Hot	G_0
Diminished sensation to either Hot or Cold	G_1
Diminished sensation to both Hot and Cold	G_2
No thermal sensation	G_3

7. Vibration Perception

Diminished vibration sensation on Rt. And Lt. extensor area of great toe of feet bilaterally	G_0
G_0 + Diminished vibration sensation on Medial malleolus of feet bilaterally	G_1
G_1+ Diminished vibration sensation on Rt. And Lt. extensor area of thumb bilaterally	G_2
G_2+ Diminished vibration sensation on of head of Ulna bilaterally	G_3

8. Pin Sensitivity

Normal sensation to superficial pin prick	G_0
Sensation only to moderate pin prick not extending whole thickness of skin	G_1
Sensation to deep skin prick extending whole thickness of skin	G_1
No sensation at all	G_3

8. Deep Tendon Reflexes

Normal all tendon reflexes	G_0
Diminished either upper limb or lower limb reflexes	G_1
Diminished both upper and lower limb reflexes	G_2
Absent all tendon reflexes	G_3

Follow up

Patients were called after an interval of 15 days to assess the effects of therapy.

Observations

In the present study, total 23 patients were registered out of which 22 patients completed the study and 1 patient did not complete the whole duration of trial and was considered dropped out.

Clinical Profile

Incidence of Symptoms

Symptoms	Number of Patients	Percentage
Numbness	12	52.17
Tingling	9	39.13
Kar Pad Daha	8	34.78
Pain	4	17.39
Gloves and Stocking	2	8.69

It was observed that 12 (52.17%) patients had numbness, 9 (39.13%) patients had tingling, 8 (34.78%) patients had kar Pada Daha, 4 (17.39%) patients had pain and 2 (8.69%) patients had feeling of Gloves and Stocking in their extremities.

Incidence of Signs

Signs	Number of Patients	Percentage
Diminished Vibration Perception	23	100
Diminished Deep Tendon Reflexes	21	91.30
Impaired Pin Sensitivity	6	26.08
Impaired Thermal Sensation	6	26.08

It was observed that 23 (100%) patients had diminished vibration perception, 21 (91.30%) patients had diminished deep tendon reflexes, 6 (26.08%) patients had impaired pin Sensitivity and 6 (26.08%) patients had Impaired thermal sensation.

RESULTS

Effect of therapy on sings and Symptoms

S. No.	Signs and Symptoms	Mean Score		% relief	±SD	±SE	't'	p
		BT	AT					
1	Numbness	1.83	0.75	59.09	0.28	0.08	11.06	<0.001
2	Kar Pad Daha	2.12	0.37	82.35	0.46	0.16	9.16	<0.001
3	Tingling	1.7	0.4	76.47	0.48	0.15	13.74	<0.001
4	Pain	2.7	0.00	100	0.86	0.5	4.5	<0.001
5	Gloves & Stockings	1.0	0.5	50	0.70	0.49	1.0	<0.5
6	Vibration Perception	5.0	4.0	19.81	0.90	0.19	7.23	<0.001
7	Pin Sensitivity	1	0.16	83	0.41	0.18	4.47	<0.001
8	Thermal Perception	1.5	0.83	44.44	0.59	0.24	5.47	<0.01
9	Deep Tendon Reflexes	3.5	2	42.87	1.05	0.22	6.65	<0.001

DISCUSSION

The present clinical trial was conducted to clinically assess the efficacy of Hydroalcoholic extract of *Dashmool*, *Pushkarmool* and *Shudhha Hingu* in capsule form and *Abhyanga*, local application of *Mash Taila* on the patients of Diabetic neuropathy. Presently there is no promising cure of Diabetic Neuropathy though there are many modern drugs which are being tried but their side effects out way the real uses. In this pursuit a humble effort was made to explore the Ayurvedic science so as to provide a better treatment with no side effects. In the present study, total 23 patients were registered out of which 22 patients completed the study and 1 patient was dropped out. The total duration of therapy was 45days,the clinical study comprised of demographic, constitutional, clinical and laboratory profiles, the conclusions drawn from the study are described as follows:-

The present clinical trial revealed that 52.17% patients had numbness, 39.13% patients had tingling, 34.78% patients had kar Pada Daha, 17.39% patients had pain and 8.69% patients had feeling of Gloves and Stocking in their extremities. 100% patients had diminished

vibration perception, 91.30% patients had Diminished deep tendon reflexes, 26.08% patients had impaired pin sensitivity and 26.08% patients had Impaired thermal sensation**.**

The response of the trial drug was found highly significant ($p<0.001$) in Numbness, Kar Pad-Daha, Tingling, Pain, Vibration Perception, Pin Sensitivity, Thermal Perception, Deep Tendon Reflexes maximum of assessment criterias but there was no much improvement in feeling of Gloves and Stockings. As the patients were taking Oral hypoglycaemics drugs under regular monitoring so fasting blood sugar was well under control. The other routine baseline haematological and biochemical investigations were normal before the therapy and remained, normal after the treatment also, so they were not altered by therapy on these profiles .It is clear from the above facts that the presently used formulation is effective in patients of Diabetic Neuropathy. No harmful side effects of the trial drug were seen during the period of study. Some more studies on larger patient samples need to be done before reaching final conclusions of effectiveness and safety of drug formulation.

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