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A CLINICAL STUDY ON THE MANAGEMENT OF DIABETIC POLYNEUROPATHY WITH RASAYANA VATI

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Abstract:

Introduction: Diabetic Polyneuropathy is one of the most common troublesome micro vascular complications of diabetes mellitus. It is nerve damaging disorders which are result in metabolic as well as vascular degeneration of neuron resulting in impaired nerve conduction. In Ayurveda, although there is no direct correlation for Diabetic Polyneuropathy but the basic Most of the symptoms mentioned under *purvarooopa* and *upadrava* of *Prameha* such as *pada daha*, *padasuptata*, and *shoola* similar to diabetic Polyneuropathy symptoms. Pathology behind it is can be studied under *madhumeha upadrava* caused by *Avarana janya vata prakopa*. Hence in diabetics, prevention and management of Polyneuropathy is of utmost importance. This condition is well managed by Ayurveda with effectively and less cost. **Materials and Methods:** It is a clinical study with pre- test and post- test design conducted in single group. *Rasayana Vati* was given in a dose of 500mg 2 tablets twice in a daily for a period of 8 weeks. All the patients were followed up for a period of 4 week and assessment was done on the basis of subjective criteria (NSS and MNSI). **Results:** The change in the values before and after treatment were assessed by the paired't' test. Statistically highly significant result was obtained in NSS (89.86%), MNSI-A (64.69%) and MNSI-B (71.69%). **Discussion:** *Rasayana vati* provide symptomatic relief in Diabetic Polyneuropathy by rejuvenation and energizing of peripheral nerves. It possesses the property of *Rasayana*, which act on *Agni* (Digestion and Metabolism) *Srotas* (Micro-circulation&Tissue perfusion) and *Mana* (Mental Competence). This property of *Rasayana vati* break down the pathogenesis of Diabetic Polyneuropathy, which is result in reduces the symptoms of Diabetic Polyneuropathy. **Conclusion:** The alternate hypothesis *Rasayana vati* is effective in the management of Diabetic Polyneuropathy is accepted and null hypothesis stands rejected.

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Rasayana vati, *Rasayana* , NSS, MNSI.

INTRODUCTION:

Diabetic Polyneuropathy is one of the most common troublesome micro vascular complications of Diabetes mellitus.¹ It is nerve damaging disorders which are result in metabolic as well as vascular degeneration of neuron resulting in impaired nerve conduction. The prevalence of diabetes neuropathies is rising with global burden of type 2 diabetes.² Given that diabetes affects approximately 264million people worldwide, it is estimated that 20-30 million people are affected by symptomatic Diabetic neuropathy.³ This neuropathy is leading independent risk factors (Hypertension, dyslipidemia, obesity, and cigarette smoking) for mortality and morbidity as a result of foot ulceration and non traumatic amputation of lower limb extremities.⁴ This makes the patient permanently immobile. There is no direct correlation of diabetic Polyneuropathy in Ayurveda. *Madhumeha* is one among the four varieties of *Vataja Prameha* which is compared to the Diabetes Mellitus of the Allied science. *Karapada Daha*, *Karapada Suptata* is explained as *Samanya Poorvaroopa* and *Madhumeha Upadrava* such as *Padadaha*, *Padaharsha* and *Padasuptata*.⁵ These can be correlated with Diabetic Polyneuropathy. The management of Diabetic Polyneuropathy is not up to the mark and associate with lots of side effects in conventional system of medicine. Keeping this view in mind *Rasayana vati* was under taken to evaluate its clinical efficacy and safety in Diabetic Polyneuropathy

Objective:

To evaluate the effect of *Rasayana Vati* in the management of Diabetic Polyneuropathy.

Materials and Methods:

Ethical clearance was obtained (PIA/IECHR/2016-17/KC/03) and this study is registered in Clinical Trial Registry of India (CTRI/2017/02/013328).

Study Design: Open clinical study.

Method of collection of data:

A series of patients of either sex of Diabetic Polyneuropathy were screened from OPD and IPD of Parul Ayurveda hospital attached to Parul Institute of Ayurveda. The study was approved by Institutional Ethics Committee (IEC). Clinical study was conducted on diagnosed cases of Diabetic Polyneuropathy fulfilling criteria of eligibility after voluntarily informed consent. The data were collected in specially designed Performa involving socio-demographic data, history, physical examination, investigations and parameters of assessment.

Diagnosed criteria: Diagnosed cases of Diabetic Polyneuropathy

Inclusion Criteria:

- Metabolically stable type 2 diabetic patients with symptoms of diabetic sensory-motor Polyneuropathy.
- Patients of either sex between the age group 35-70 years.

Exclusion criteria:

- Patients who are treated with Insulin.
- Patients with other metabolic or endocrine disorders.
- Patients with other causes of Polyneuropathy.
- Patients suffering from infectious diseases.
- Patient with non-healing ulcer/ulcers.
- Patient with Disabling Diabetic Polyneuropathy(Dyck's staging)⁶

Criteria for Assessment:

- Neuropathy Symptom Score (NSS)⁷
- Michigan Neuropathy Screening Instrument (MNSI)⁸

Time Points:

The outcomes were measured after screening at Baseline (BT) and at the end of 8 weeks (AT)

Intervention:

The trial drug *Rasayana Vati* chosen for present study an herbal preparation containing *Amalaki*, *Gokshura* and *Amrta* in equal quantity. 2 tablets of 500mg twice daily after food along with warm water was given for 8 weeks.

(Note: The anti-diabetic regimen of the selected patients was not altered during study. Additional dietary or life style restrictions were prescribed.)

Procurement of the trial drugs:

The ingredients of *Rasayana vati* modified form of *Shwadamshtradi Choorna*⁹ containing *Gokshura*, *Amalaki* and *Amrita*. This drug were identified Pharmacognostically and it was taken in equal quantity. They processed into tablet as per SOP mentioned in AFI at pharmacy attached to Parul Institute of Ayurveda.

Observation and Result:

Demographics Profile:

In the present study, there were 30 patients were enrolled and out of them 46.67% patients were of >50 years old, 60% were male, 23(76.67%) of population were Hindu, 26(86.67%) were married, 20(66.67%) patients were belongs to Middle Class Family, 14(46.67%) of subjects had Diabetes mellitus type 2 for 1-5 years, 16(53.4%) had their blood sugar range between 250-350 mgdl, patients were having food at irregular timings 12(40.0%),19(63.3%) were following irregular *Vyayama* routine, 15 (50%) had given positive family history of diabetes. Among the included patients, maximum had BMI of 20-25Kg/m², i.e., 17 (56.7%).

Clinical profile:

Neuropathy symptoms score and Michigan Neuropathy Screening Instrument Part A & Part B is used to assessment of severity of neuropathic symptoms. In this study maximum number of the patients 25 (83.33%) scored as with severe symptoms in NSS. Maximum number of included patients 30(100%) was scored 5-10 in the history questionnaire of MNSI and majority 15 (50%) scored 5-10 in the physical examination (assessment of Vibration perception, ankle reflexes and 10g monofilament testing) part of MNSI.

Distribution of Patients based on clinical features:

Sensory symptoms with duration: In this study maximum number of included subjects 25(83.33%) complained that burning pain is the most troublesome complaint among positive sensory symptoms. Tingling was complained by 25(83.33%), 17(56.67%) was aching and 18(60%) was complained Numbness as the major problem 2(6.67%) of included subjects had loss of balance as the chief negative sensory symptom. Majority of the people suffered with sensory symptoms of Diabetic Polyneuropathy for less than one year i.e.18(60%), it had 11(36.67%) in between two year to four years and 1(3.33%) were suffering from more than four years.

Motor symptoms with duration: In this study, maximum motor symptoms observed were difficulty in climbing up/downstairs in 30 cases (100.00%). 7(23.33%) complained of impaired fine hand co-ordination and difficulty to turning keys or opening jars were seen in 8(26.67%) patients. 2(6.66%) Flood slapping was observed and Difficulty to raise hands above shoulders was observed in 2(6.67%) patients. Majority of the people suffered with motor symptoms/signs of Diabetic Polyneuropathy for less than one year, i.e. 22(73.33%) , 8(26.67%) had it for more than two year to four years.

Statistical analysis:

The obtained information was analyzed statistically in term of mean score, standard deviation, and standard error. Paired 't' test was carried out. The result obtained is presented in the table and figures given below.

Effect of therapy:

Parameters	Mean		%	SD	SE	T	P
	BT	AT					
NSS	7.567	0.767	89.86%	1.375	0.251	27.094	<0.001
MNSA-A	9.533	3.367	64.69%	1.802	0.329	18.744	<0.001
MNSA-B	5.533	1.567	71.69%	2.109	0.385	10.303	<0.001

Discussion:

Diabetic Polyneuropathy is a sequel to *madhumeha* which occurs due to further vitiation of *doshas* or due to *vyadhi karshana*. Diabetic Polyneuropathy is believed to occur due to *Avrana janya vata prakopa*. Vitiating *vata* damages nervous tissues by local inflammatory process (*shoth*) simultaneously *Avrana* causes *sroto avrodh* (obstruction in micro channels) which lead to malformation of preceding *dhatu* (progressive nutrition of tissues) leads to further *dhatu kshya* (emaciation at tissue level as well as at micro levels). which produces symptoms like *daha* (burning sensation), *suptata* (numbness), *harsha* (tingling sensation), *shosha* (wasting), and *dourbalya* (weakness).

Rasayana vati provide symptomatic relief in Diabetic Polyneuropathy by rejuvenation and energizing of peripheral nerves. It possesses the property of *Rasayana*,¹⁰ which act on *agni* (Digestion and Metabolism) *srotas* (Micro-circulation&Tissue perfusion) and *mana* (Mental Competence). The property of trial drugs is nothing but *anabhishtyandi dravyas* dominated by *snigdha*, *guru guna* which help in *shamana* of vitiated *vata*, *Kapha*, *Pitta avirodhi* and *srotoshodhana*¹¹⁻¹³ which help in remove the *avarana* caused by *vata*. Also help in circulation of nutrition needed to provide nourishment to the body tissues and tissue perfusion. *Rasayana* promotes nutrition to *dhatu*s after *medas* which are deprived of nourishment in diabetes which is result in reduced the symptoms of diabetic Polyneuropathy.

Conclusion:

The pathogenesis of diabetic Polyneuropathy is *Avarana janya vata prakop*. The present study shows that the selected drug is well documented in classical text of Ayurveda. After evaluating the observation of present series of investigating it is conclude that the trial drug '*Rasayana vati*' has beneficial

role in reducing the severity of all symptoms of subjective parameters (NSS & MNSI) of Diabetic Polyneuropathy.

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