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A CLINICAL STUDY OF PRAMEHA UPADRAVA WITH SPECIAL REFERENCE TO THE ROLE OF VASANTKUSUMAKAR RAS IN DIABETIC NEUROPATHY

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ABSTRACT

Diabetic neuropathy is a disorder of somatic or autonomic parts of the peripheral nervous system occurring in setting of Diabetes mellitus with the exclusion of other causes of neuropathy. It's a relatively early and most common long-term diabetic complication affecting almost every peripheral and autonomic nervous tissue. The present study aimed to undertake a clinical study of *Prameha Upadrava* with special reference to Diabetic neuropathy and its management with *Vasantkusumakar Ras,* studying primarily the effect on symptoms of peripheral sensori-motor Diabetic Neuropathy. It was open comparative clinical study where *Vasant Kusumakar Ras* in Group A was compared with the management as advised by the neurologist in Group B. OHA assured a good glycaemic control in both groups. EMG NCV studies were performed along with assessment of the clinical symtomatology. Group A patients showed excellent improvement in almost all the symptoms, while EMG and NCV studies showed mild to moderate improvements in Group A. Although, there was a good symptomatic relief in a few symptoms in Group B, EMG and NCV studies revealed no significant improvement. Thus, *Vasantkusumakar Ras* proved to be a potent remedy for Diabetic complications more so when it comes to Diabetic Neuropathy.

Keywords: Diabetic Neuropathy, *Prameha Upadrava*, *Vasant kusumakar Ras*

INTRODUCTION

Diabetes Mellitus is associated with increased mortality and a high risk of developing nephropathy, retinopathy, neuropathy and cardiac complications leading to premature disability and death. Diabetic neuropathy as defined by San Antonio Consensus is a disorder of somatic or autonomic parts of the peripheral nervous system occurring in setting of Diabetes mellitus with the exclusion of other causes of neuropathy [1]. Diabetic Neuropathy is a relatively early and most common long-term diabetic complication [2] affecting almost every peripheral and autonomic nervous tissue. It is a demonstrable disorder, which occurs in Diabetes without any other evident cause. Diabetic neuropathy is one of the major factors causing foot

problems leading to lower limb amputations in diabetics. The rate of lower limb amputation is about 40 times higher in diabetics than in non-diabetics [3].In a prospective study of Diabetic patients, Pirate et al found a prevalence of neuropathy of 8 % at the time of diagnosis; and the incidence of neuropathy increased with the duration of Diabetes. It is estimated that 10% to 65% of diabetic patients have some form of neuropathy in due course of Diabetes.[4] The increasing prevalence of diabetic nerve disease with its severity is thought to be associated with-Poor glycaemic control, increasing age of the patient, increasing duration of Diabetes, presence of Cardiovascular diseases, presence of dyslipidemia, positive smoke history etc.[5] The longer impact of inadequately managed *Prameha* leads to various *upadravas,* which point towards the complications resulting from diabetes mellitus. The symptoms or associated illnesses which remain present even after a long duration of the Primary disease and these symptoms or associated diseases get relieved by treating the underlying disease are termed as *Upadrava*. *Acharya Charak* has talked of *Prameha upadravas* immediately after having given detailed description of *Prameha Purvaroopa*.[6] One can understand the importance given to *Prameha Upadravas* by the fact that *Acharya Sushrut* and *Acharya Vagbhatta* have elaborately described *Prameha Upadravas* in their *doshik* classifications.

Upadravas like *Hastapada Daha (*Burning of soles and palms), *Chimchimayan* (Tingling Sensation), *Suptata* (Numbness), *Shool* (Pain), *Daurbalaya* (Weakness), *Klaibya* (Impotency), *Bastimehanshool* (Pain in bladder region and external urethra), all correlate to the symptoms of diabetic neuropathy.

Modern science fails to understand exactly the basic patho physiology leading to the development of diabetic neuropathy. As a consequence the modern management for diabetic neuropathy is still under dilemma. Modern science has only reached to a position of providing symptomatic relief to Neuropathy patients. It has been emphasized that a good glycaemic control in Diabetic patients only helps in slowing down the progression of Diabetic neuropathy. Owing to problem occurring in the management of Diabetic Neuropathy, it is imperative to explore alternative efficacious drugs to tackle Diabetic Neuropathy.

The present study entitled "A Clinical Study of *Prameha Upadrava* with Special Reference to the Role of *Vasantkusumakar Ras* in Diabetic Neuropathy" aimed to undertake a clinical study of *Prameha Upadrava* with special reference to Diabetic neuropathy and its management with *Vasantkusumakar Ras*. The study concentrates on Peripheral neuropathy especially by considering the experience of research work done by previous scholar. This study aims to establish the effect of *Vasantkusumakar Ras* in the management of Diabetic neuropathy in comparison with the established treatment.

MATERIALS AND METHODS

Type of study: Comparative open randomized type of study.

Centre of study:

1. M. A. Podar Hospital, Worli, Mumbai-18.
2. Sushrusha Co-operative Hospital Ltd., 698-B, Ranade Road Dadar, Mumbai-28.

Selection of cases: Patients with good control of blood sugar with O.H.A. (Oral Hypoglycemic agents) presenting symptoms of Diabetic Neuropathy selected from M.A. Podar Hospital, were subjected to clinical and objective neuro-

logical examination at Sushrusha Hospital in collaboration with the Neurologist. EMG nerve conduction studies of all the patients were essentially performed and at the end of the trial. Presence of any other disease was ruled out. To assess the subjective feature more precisely, the clinical symtomatology was graded into four grades (0-3) scale on the basis of severity and duration.

Sample Size: 40 patients (20 in each group)

Grouping of Patients- Randomly selected Patients were divided into two groups.

1. Group A- 20 patients were given the drug *Vasant Kusumakar Ras* .
2. Group B-20 patients were given standard conventional treatment as suggested by neurologist.

Inclusion Criteria:

1. Established cases of diabetic neuropathy or diagnosed after proper examination were selected for the trial.
2. Cases from both sexes between the age group of 30 to 70 years were considered.
3. Glycaemic status of all the patients included in the trial had to be adequately controlled.

Exclusion Criteria:

1. Patients with severe acute complications of diabetes mellitus.
2. Patients below 30 yrs of age and above the age of 70 yrs.
3. Patients presenting acute and severe symptoms of diabetic neuropathy requiring urgent management.
4. Patients suffering from tuberculosis, kidney disorders, hepatic ailments, pregnancy and lactation.

Drug Preparation:

The drug *Vasant Kusumakar Ras,* a *Kharaliya Rasayan* type of drug was prepared at Dabur Pharmaceuticals, New Delhi, India as per the reference in *Yogratnakar* in *Prameha Chikitsa Adhyaya*[7] The market packing of *Vasant Kusumakar Ras* phials was supplied as assistance in pursuit to have a standard research.

Composition of the drug *Vasant Kusumakar Ras:*

Table1: Showing Composition of the drug *Vasant Kusumakar Ras* according to Yogaratnakar

Ingrédients	**Proportion**	**Percentage**
Swarnabhasma (Gold-Aurum)	2 Parts	6.9
*Rajatbhasma (*Silver/Argentum*),*	2 Parts	6.9
Vangabhasma (Tin-Stannum)	3Parts	10.34
Naga bhasma (Lead-Plumbum)	3 Parts	10.34
Kantalohabhasma (Magnetic iron calx)	3 Parts	10.34
Paradbhasma (Mercury/Hydrargyrum)	4 Parts	13.79
Abharak bhasma (Mica)	4 Parts	13.79
Praval bhasma (Coral)	4 Parts	13.79
Mauktik bhasma (Pearl)	4 Parts	13.79

Bhavana (trituration) *dravyas* of *Vasant Kusumakar Ra*s in the chronological order are *GoDugdha* (Cow's milk), *Ikshuras* (Sugarcane juice), *Vasa patra Swaras (*Adhatoda vasica), *Kamal Pushpa* (Nelumbo nucifera), *Usheer* (Vetivera zizaniodes), *Haridra* (Curcuma longa), *Kadlikand swara*s (Musa paradisiaca). The grinded mixture of the *bhasmas* was proc-

essed with the liquids in the chronological order given above. The trituration process was carried out seven times separately with each *bhavana dravya.*

***Punarbhavana* (re-trituration) :-**

The mixture was again re- triturated with juice of *Gulab* (Flowers of Rose –Rosa damascene) and was then dried and stored.

Dosage: 125-mg bd.

1st dose early morning on empty stomach (*Rasayana kala*)

2nd dose in the evening preferably empty stomach. (*Rasayana kala*)

Anupana: Plain water.

Diet: Diet already being advised by a Diabetologist/Physician was continued.

Duration of treatment: 12 weeks.

Pathological assessment of Diabetic neuropathic patients:

1. EMG nerve conduction studies were done at entry and at end of the study.
2. Blood sugar (Fasting and Post Prandial) and urine sugar were done every 4 weeks.
3. BUN ,S.Cholestrol, S.Trigyceride, S.Alb, S.Gb. and S.Cr. were done at entry and at end of the study.
4. CBC, Hb % and ESR were done every 4 weeks.
5. Glycosylated Hb % was estimated at the entry point and at the end of the study

Follow Up: After every 4 wks**.** Good glycaemic control was assured for all the patients under trial.

Parameters of assessment:

Patients were monthly assessed under two heads:

1) Subjective improvement.
2) Objective improvement.

1) Subjective improvement-

The present study aimed at studying primarily the symptoms of peripheral sensori-motor Diabetic Neuropathy for the purpose of clinical evaluation. To assess the improvement in the clinical symptoms of Diabetic Neuropathy different symptoms were arbitrarily graded into four grades scale (0 to 3) on the basis of severity and duration.

GRADATION OF SYMPTOMS

Table2: Showing Symptoms Arbitrarily Graded Into Four Grades Scale (0 To 3) On The Basis Of Severity and Duration.

Sr.No.	SYMPTOM	GRADE 0	GRADE 1	GRADE 2	GRADE 3
1.	Pain (Chronic / Acute in the limbs and joints)	No Pain	Intermittent Pain without disturbing routine activity	Continuous Pain without disturbing routine activity.	Severe continuous Pain disturbing normal activity
2.	Burning sensation (Of the peripheries)	No Burning sensation	Intermittent Burning sensation without disturbing routine activity	Continuous Burning sensation without disturbing routine activity.	Severe continuous Burning sensation disturbing normal activity
3.	Tingling Sensation (Of the peripheries)	No Tingling Sensation	Intermittent Tingling sensation without disturbing routine activity	Continuous Tingling sensation without disturbing routine activity.	Severe continuous Tingling sensation disturbing normal activity
4.	Numbness (of extremities)	No Numbness (symmetrical or	Intermittent numbness without dis-	Continuous Numbness without disturb-	Severe Numbness disturbing normal

		asymmetrical)	turbing routine activity	ing routine activity.	activity
5.	Hyperaesthesia (Of the peripheries)	No Hyperaesthesia	Intermittent Hyperaesthesia without disturbing routine activity	Continuous Hyperaesthesia without disturbing routine activity.	Severe continuous Hyperaesthesia disturbing normal activity
6.	Hypoaesthesia (Of the peripheries)	No Hypoaesthesia	Intermittent Hypoaesthesia without disturbing routine activity	Continuous Hypoaesthesia without disturbing routine activity.	Severe continuous Hypoaesthesia disturbing normal activity
7.	Dysesthesia (Of the peripheries)	No Dysesthesia	Intermittent Dysesthesia without disturbing routine activity	Continuous Dysesthesia without disturbing routine activity.	Severe continuous Dysesthesia disturbing normal activity
8.	Weakness (both generalized and of a particular part)	No Weakness	Weakness during routine activity.	Routine activity is disturbed due to weakness but the patient is not bed ridden.	Patient becomes bed ridden or even has to be hospitalized.
9.	Cramps	No cramps while walking.	Cramps after walking for about 1 Km.	Cramps after walking for about 1/2 Km.	Cramps even without walking.
10.	Tremors (Of the extremities)	No Tremors	Intermittent Tremors without disturbing routine activity	Continuous Tremors without disturbing routine activity.	Severe continuous Tremors disturbing normal activity

Signs of Diabetic neuropathy were also assessed after every four weeks.

1. Inspection of the feet was done for Skin status, Sweating, Infection and ulceration, Calluses/blistering, Deformity, Muscle atrophy, Arches
2. Neurological tests such as, Pin prick test, Light touch, Vibration test. Joint perception, Temperature perception, Ankle reflex were done. Superficial reflexes and muscle power of the extremities were monthly monitored in each patient.

Objective Assessment:

The pre and post EMG Nerve Conduction were graded and compared to assess the effects of drug.

CLINICAL CLASSIFICATION OF DIABETIC NEUROPATHY:

Table 3: Showing clinical classification of diabetic neuropathy

Grade	Proposed Disease Severity Level	Findings Observable upon EMG Nerve Conduction
0	No apparent neuropathy	No abnormalities.
1	Mild Diabetic neuropathy	10% to 20% drop in amplitude and Nerve Conduction Velocity.
2	Moderate Diabetic neuropathy	20% to 50% drop in amplitude and Nerve Conduction Velocity.
3	Severe Diabetic neuropathy	More than 50% drop in amplitude and Nerve Conduction Velocity.

Assessment in the shift of Grades in EMG and Nerve Conduction Studies

Almost in all patients the median nerve in upper limb while Peroneal and Sural nerve in lower limb was studied. At the same time according to the symptomatology other nerves like Radial, Ulnar, Tibial nerves, etc were studied. Improvement in NC Studies was based on improvement in Amplitude and Nerve Conduction Velocities (NCV). The assessment is based on three basic categories Mild, Moderate and Severe, the parameters of these assessments is as follows.

Mild Improvement-More than 10% and upto 20% improvement in amplitude and NCV.

Moderate Improvement - 20% to 30% improvement in amplitude and NCV.

Very Significant Improvement -More than 30% improvement in amplitude and NCV.

Assessment of Tolerability:-Effect of the drug and presence of any adverse effects of the drug, on all the patients of both groups was observed. Special inquiries were made for the presence of symptoms like Vomiting, Loose motions, Headache, Itching, symptoms pertaining to digestive system, Oliguria, Detoriation of vision or its sudden loss and signs of gangrene.

Premature Discontinuation: Reasons for the premature discontinuation of the drug in any treatment groups were studied.

Assessment of Drug response: Assessment of drug response was done on the basis of:

1) Duration of the disease and age of the patient.
2) Severity of the disease and the complication.
3) Effect on overall health during trial of the drug.
4) Effect on Diabetic Neuropathy symptoms with subjective and objective analysis.
5) Effect of the drug on Blood sugar levels was also evaluated.

Statistical analysis: Wherever, possible efforts were made to present the data in the form of T tests, probability co-relations, and other statistical parameters. The mean of the difference between initial value and readings of 4 wks, 8 wks and 12 wks, was calculated.

RESULTS

Subjective Assessment:

Group A- Symptomatic Improvements as Per Mean Grade Score Of Symptoms Of Diabetic Neuropathy

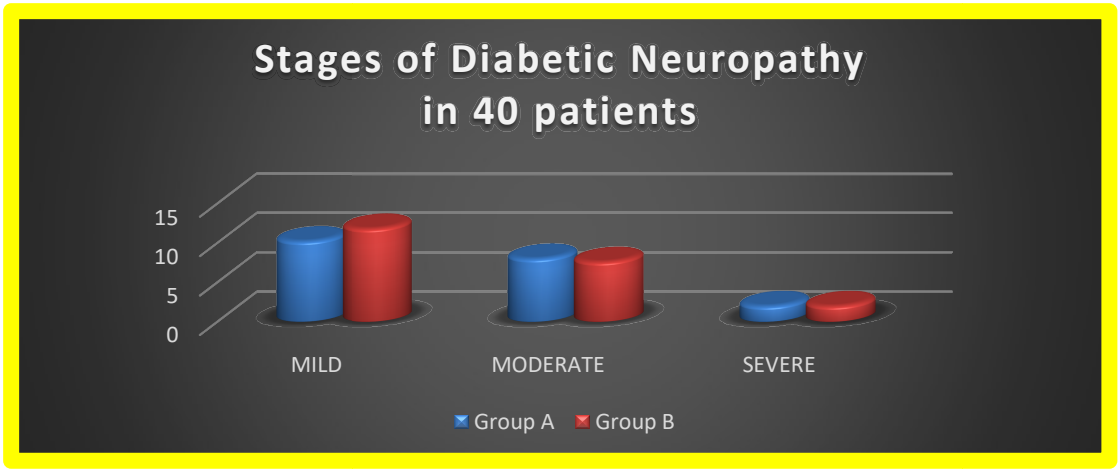
Table 4: Showing symptomatic improvements as per mean grade score of symptoms of diabetic neuropathy in Group A.

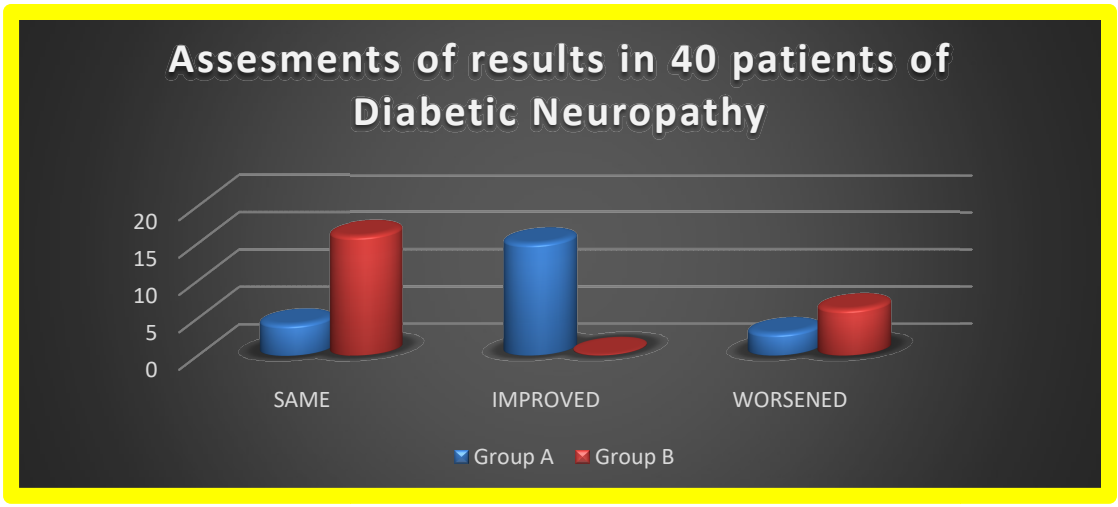
Sr.No	SYMPTOM	INITIAL	AFTER 12 WKS
1.	Pain (*Vedana)*	2.05 ±0.85	0.53±0.63
2.	Burning sensation (*Hasta pada Daha)*	2.56 ±0.5	1.25 ±0.27
3.	Tingling Sensation (*Hasta pada Chimchimayana)*	2.0 ±0.85.	1.2 ±0.5
4.	Numbness(*Suptata)*	1.9 ±0.97	1.05 ±0.66
5.	Hyperaesthesia(*Atisparsh gyan)*	1.2 ±0.67	0.66 ±0.66
6.	Hypoaesthesia(*Atisparsh gyan)*	1.73 ±0.59	1.67 ±0.56
7.	Weakness(*Daurbalaya)*	2.46 ±0.74	1.13 ±0.25
8.	Cramps(*Pindikodweshtan)*	0.8 ±0.77	0.20 ±0.41
9.	Tremors(*Kampa)*	0.46 ±0.51	0.13 ±0.35

Group B -Symptomatic Improvements as Per Mean Grade Score of Symptoms of diabetic neuropathy

Table 5: Showing symptomatic improvements as per mean grade score of symptoms of diabetic neuropathy in Group B

Sr. No.	SYMPTOM	INITIAL	AFTER12 WKS
1.	Pain (*Vedana)*	1.75 ±0.96	1.45 ±0.88
2.	Burning sensation (*Hasta pada Daha)*	0.15±0.43	2.2±0.56.
3.	Tingling Sensation (*Hasta pada Chimchimayana)*	0.68±0.83	0.42±0.56.
4.	Numbness(*Suptata)*	0.29 ±0.79	1.2 ±1.98
5.	Hyperaesthesia(*Atisparsh gyan)*	0.39±0.59	0.25 ±0.38.
6.	Hypoaesthesia (*Atisparsh gyan)*	1.26 ±0.88	1.33 ±0.81
7.	Weakness (*Daurbalaya)*	0.05±0.16.	0.15±0.67.
8.	Cramps (*Pindikodweshtan)*	1.05 ±0.71	0.05 ±0.16
9.	Tremors(*Kampa)*	0.93 ±0.88	1.06±0.59.





Objective Assessment:

Haemogram: All patients of Diabetes included in the trial were evaluated for Blood cholesterol, triglycerides, BUN, Blood Urea, Haemoglobin, Serum Albumin and Serum Globulin. These investigations were done at the entry point and at the end of the trial. There were no significant changes in any of the blood values.

Blood Sugar Levels in the patients of Diabetic Neuropathy: All the patients of both groups were assessed for their Blood Sugar Levels at the entry point and at a subsequent follow up of 4 weeks, till 12 weeks. Also assessment of Glycosylated Haemoglobin was done initially and at the end of the trial. Mean Glycosylated Haemoglobin in the group of *Vasant Kusumakar Ras* was 7.12% initially while finally it was 6.96%. In the comparative group mean Glycosylated Haemoglobin was 6.7% initially while at the end of the trial mean Glycosylated Haemoglobin was 6.45%.

BLOOD SUGAR LEVELS OF 40 PATIENTS OF DIABETIC NEUROPATHY

Table 6: Showing the blood sugar levels of 40 patients of diabetic neuropathy

Sr.No	Interval	Group A (Fasting)	Group A (Post prandial)	Group B (Fasting)	Group B (Post prandial)
1.	Initial	93.33 mg % ±14.43	133.33 mg % ±19.15	107.2 mg % ±15.95	130.2mg % ±12.41
2.	After 4 weeks	102 mg% ±16.79	135.66 mg % ±15.57	110.5 mg% ±14.25	129.2 mg % ±22.54
3.	After 8 weeks	107 mg% ±18.91	142.4 mg % ±18.05	111.2 mg% ±22.86	138 mg % ±24.93
4.	After 12 weeks	115.4 mg% ±15.90	137.9 mg % ±23.10.	103.6 mg% ±22.92	138.2 mg % ±31.58.

Electromyography (EMG) and Nerve Conduction Studies Assessment:

Group A: EMG and NCV studies at the entry point and at the end of the trial revealed, 11 patients showing improvement in the condition of Diabetic peripheral neuropathy. Two patients of these having mild sensory motor neuropathy initially were reported as having reverted back to normal findings at the end of the trial. Similarly one patient having bilateral S1 root lesion was reported as having reverted to normal study. Two patients having moderate neuropathy showed marked improvement with final report as mild neuropathy. One patient suffering from disabling neuropathy showed mild improvement. Of the remaining five patients having mild neuropathy, four showed mild improvement while one patient showed marginal improvement. Among the remaining 9 patients, four patients showed no changes while three patients reported improvement in nerve conduction study of single nerves. Two patients showed deterioration in the neuropathic condition.

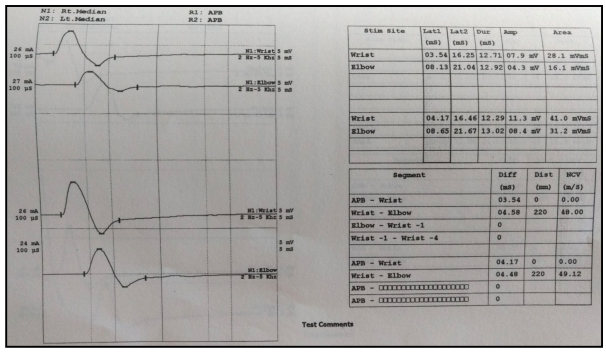
Group B: EMG and NCV studies at the entry point and at the end of the trial revealed no significant improvement in the condition of Diabetic peripheral neuropathy. Five patients having mild sensory motor neuropathy showed progression in the disease. Two patients of severe neuropathy showed almost no changes in the EMG and NCV studies. While among the 13

patients, 7 of moderate peripheral neuropathy and 6 of mild peripheral neuropathy in this group reported similar condition initially and after the trial.

EMG Study Report – Group A: Initial Study

Name: Surekha Unwarkar Date: 11-Jun-2002

This study detects a mild axonopathic (recent origin) sensorimotor neuropathy.



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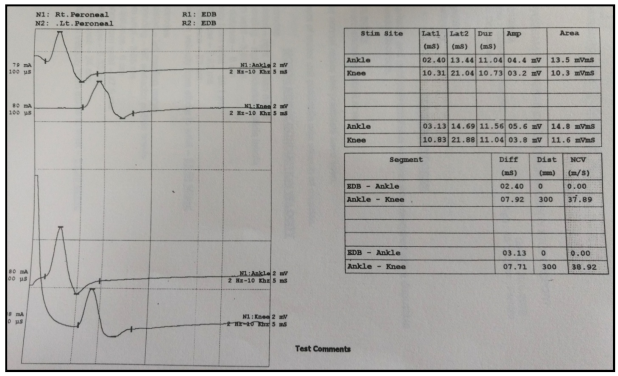

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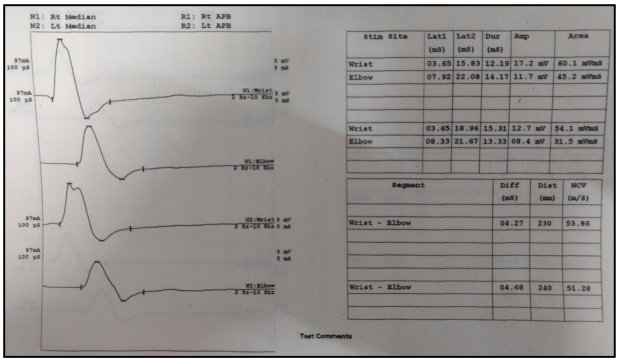

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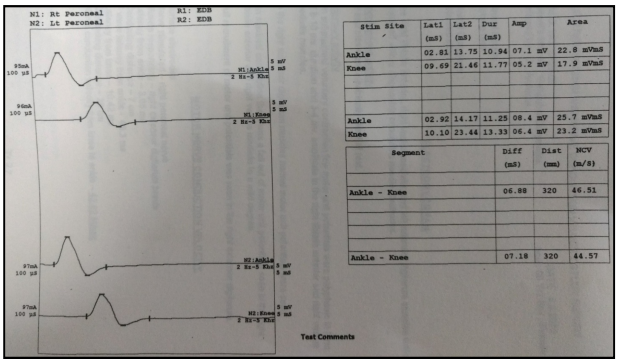

DISCUSSION

Prameha is *Tridoshik* complex disorder with varied predominance of *doshas*. In *Prameha* there is an involvement of all the three *Doshas* and all the *Dhatus* except '*Ashti Dhatu'*. From the *Prameha* pathogenesis it appears that all the three *Doshas* especially *Kapha Dosha* causes a progressive loss of *Dhatus* such as *Meda ,Rakta, Shukra, Ambu, Vasa, Lasika, Majja, Rasa, Oja, Mamnsa* through the *Mutravaha strotasa*. Hence *Acharya Charak* has given the following *Prameha* pathogenesis on the basis of the specific aetiological factors .*Kapha* aggravating

ahar vihar vitiates *Kapha*, *Meda, Mansa and Kleda* in the *basti* leading to *Kapha Prameha*. Similarly, the *Pitta* aggravating *ahar vihar* vitiates *Pitta , Meda, Mansa and Kleda* in the *basti* leading to *Pitta Prameha*. When there is *Kapha* or *Pitta kshaya*,as compared to *Vata*, the aggravated *Vata* excretes the *dhatus* through the urine resulting in *Prameha*[8].*Charak* states that *Vata, Pitta and Kapha* when vitiated separately due to their respective vitiating causes, they first affect *meda, dhatus*. These vitiated *Doshas* and excited *Dhatus* then jointly excite the other liquid *Dhatus* to produce 20 sub types of *Prameha*[9].

The present study entailed "A study of *Prameha Upadrava* with special reference to the role of *Vasant Kusumakar Ras* in Diabetic Neuropathy." aimed to study and to find out the effect of the herbo-mineral preparation, '*Vasant Kusumakar Ras'* in this complication. Ayurveda believes that the management of the underlying disease will manage the complications *(upadrava*).But if these *Upadravas* become too distressing and life threatening to the patient they have to be managed immediately, separately and independently. An elaborate description of *Prameha upadravas* is available in all the classical texts of Ayurveda . Symptoms like *Hasta pada Daha, Chimchimayana, Stamba, Shaithliya, Shool, Daurbalaya, Pindikodweshtan, Kampa*, all point towards *upadravas* or complication of Diabetes i.e. Diabetic Neuropathy more so towards Peripheral Diabetic Neuropathy.

Clinical evaluation of the drug was done in cases of Diabetic peripheral neuropathy with a comparative study of the treatment prescribed by the neurologist. Good glycaemic control was assured in both the groups. Patients of Diabetic peripheral neuropathy under comparative treatment in this study showed unstable improved change*s* in the symptoms like Tingling Sensation, Hyperaesthesia, Hypoaesthesia, Pain and Cramps. In group B patients- Tingling Sensation, Hyperaesthesia, Hypoaesthesia, Pain, and Cramps improved significantly but even one skipping of dosage aggravated these symptoms. While the symptoms like Burning Sensation, Numbness, Weakness and Tremors responded poorly. On the other hand patients of Group A treated with *Vasant Kusumakar Ras* showed significant improvement in all the symptoms. Symptom, which failed to respond satisfactorily, was Tremor. There was no patient suffering from Dysesthesia in either group. Objective assessment by Electromyography and Nerve Conduction Studies showed mild to moderate improvements in Group A while there was almost no significant changes in EMG and NC Studies of group B patients.

Untoward effect was not evidenced in any of the patients in the study. Complete Haemogram of Renal and Hepatic Functions showed that the drug has not produced any toxicity or impairment of function in patients treated for a period of 12 weeks.

Mechanism of the action

The possible mechanism of the action of *Vasant Kusumakar Ras* is possibly by the combined effects of each of the ingredients of the drug. The drug itself is a potent anti diabetic (*Meghana*) agent. All the ingredients have a property of acting at the level of the *dhatus*, imparting them strength, preventing their *shaithilya* and also their *ksharan* through the urinary system. All ingredients possess a *Rasayana* property, thus restoring the lost strength and replenishing the lost *dhatus*. *Vasant Kusumakar Ras* being a *Swarna kalpa* has all the added benefits of any *Swarna kalpa. Swarna bhasma*

has a special quality of improving the *Rasa rakta sancharan in Shira Pradesh* thus enriching the *indriyas* and in turn improving the sensory and motor functions [10]. The unique property of *Swarna bhasma* mentioned about pacifying the aggravated *vayu*, nourishing (*pushti)*, the *ksheen vayu* and maintaining the *sam avastha of prakrut vayu* can be supposed to normalize the neuropathic symptoms of *Prameha* patients[11]. It is strongly believed that the presence of Swarna bhasma may potentiate the action of the drug. Ingredients like *Swarna, Rajat, Loha, Praval* and *Mauktik* have beneficial effect on the nerves. Ingredients like *Swarna, Rajat, Abhrak, Praval, Mauktik, Naga* and *Vanga* act directly on the symptoms of neuropathy and thus relieve them. Also *Bhavana* dravyas like Cow's milk, Sugarcane juice, *Kamal Pushpa, Usheer swaras*, etc are said to be good for the neuropathic symptoms related to *Pitta dosha*. The ingredient *Vanga bhasma* is especially useful in *mutravaha strotodushti* and it also improves the strength of *indriyas* and nourishes the body [12]. Thus *Vasant Kusumakar Ras* is beneficial in the *dhatushaithilya*, *dhatukshya, dhatuksharan* and *ojodushti avastha* of diabetic neuropathy. Thus from the vast treatise of Ayurveda keeping all the Ayurvedic principles in mind in the management of *Prameha* and its *upadravas, Vasant Kusumakar Ras* becomes a good candidate for being the drug of choice in Diabetic neuropathy.

The study is a step in the series of developments in the field of Ayurveda to find satisfactory solutions in the treatment of this particular diabetic complication, which poses a challenge. Specific targeted studies with more number of subjects and longer duration trials should be further carried out to establish, on strong footing the use of *Vasant Kusumakar Ras* as the drug of choice in Diabetic neuropathy

CONCLUSION

The present study was primarily carried out with the objective of evaluating the effect of *Vasant Kusumakar Ras* in *Prameha upadrava* with special reference to diabetic neuropathy. Simultaneously, it appeared necessary to review the disease *Prameha* described in the *Ayurvedic Samhita granthas* and their commentaries. This included understanding the *Samprapti*, the *Doshas* and *Dushyas* involved the development of complications and their co- relation to Diabetes mellitus and its complication Diabetic neuropathy. An effort was also made to review Diabetic neuropathy in reference to *Ayurvedic* literature.

The patients in Group A were given *Vasant Kusumakar Ras* while the patients in Group B were given the modern prescription as advised by the neurologist. Neurologist would essentially prescribe one of the following drugs; gammalinolinic acid, mecobalamin, aldose reductase inhibitors, multivitamins especially B1, B6, B12, antidepressants, etc. The drug in Group A always was *Vasant Kusumakar Ras* which was compared with the routine management of Diabetic neuropathy patients as advised by the neurologist treating every case as was deemed fit to them in Group B. Oral hypoglycaemic agents assured a good glycaemic control in both groups. Patients suffering from Type 2 diabetes were only included in the trial.

Although there was a good symptomatic relief in a few symptoms of neuropathy in Group B, EMG and NCV studies at the entry point and at the end of the trial revealed in these selected patients, no significant improvement in the condition of Diabetic peripheral neuropathy. The symptomatic relief in the patients of Group B appeared to be more so because of a good glycaemic control.

The patients in Group A showed excellent improvement in almost all the symptoms. The more bothering symptoms of neuropathy were pain, burning sensation, tingling sensation and weakness. All these symptoms appeared to have improved in four to six weeks. The EMG and NCV studies at the entry point and at the end of the trial in Group A revealed changes as below:

The categorization of 11 patients showing improvement in the condition of Diabetic peripheral neuropathy was observed as -Fair improvement in 5 patients, Good improvement in 3 patients, excellent improvement in 3 patients.

Among the remaining 9 patients EMG and NCV studies at the entry point and at the end of the trial revealed changes observed as - Single nerve improvement in 3 patients, No change in 4 patients and Deterioration in 2 patients.

This probably suggests the need to administer the drug for a longer duration and number of patients who have to be objectively analyzed should be more.

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