

A COMPARATIVE CLINICAL STUDY TO ASSESS THE EFFECT OF DHANYAMLA DHARA AND DASHMOOLA KASHAYA DHARA IN SIGNS AND SYMPTOMS OF DIABETIC SENSORY NEUROPATHY

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ABSTRACT

Background: As the civilization improved, diseases also evolved as a negative effect of development. Among them diabetes mellitus is one and prime. Principally diabetes mellitus is a metabolic disorder with variable clinical manifestations and progression. The longstanding hyperglycemia adversely affects multiple organ systems especially kidney, eyes and sensory nerves. Diabetic Sensory Neuropathy leads to burning sensation in soles of feet and Paraesthesiae. Diabetic Neuropathy is considered as *Upadrava* of *Madhumeha* and is analyzed under *vikar-prakruti*, *samuthan vishesha* and *adhistan*. In conventional medicine, medicines used for diabetic sensory neuropathy are for symptomatic relief. All these drugs have their side effects. Hence there is need to find out safer and effective treatment from the sources other than conventional medicine. Hence the management of DSN through *Ayurvedic* medications and procedures is most needed currently. **Aim and Objective:** To compare and evaluate the efficacy of *Dhanyamla Dhara* and *Dashmoola Kashaya Dhara* in Diabetic Sensory Neuropathy in detail. **Methodology:** For these 40 patients were selected dividing 20 in each group. Group A treated with *Dhanyamla Dhara* and Group B treated with *Dashmoola Kashaya Dhara* for 21 days. **Results and Conclusion:** *Dhanyamla Dhara* and *Dashmoola Kashaya Dhara* showed good results in their respective *Kalpas* but when we compare with each other both groups showed statistically not significant results on parameters of the study. But Clinically *Dhanyamla Dhara* shown more efficacy than *Dashmoola Kashaya Dhara*.

Keywords: *Karpada Daha*, *Dourbalya*, *Suptata*, *Haritkyadi Yoga*, *Dhanyamla Dhara*, *Dashmoola Kashaya*, *Gandharvahastadi Kashaya*.

INTRODUCTION

Diabetes mellitus is caused by a spectrum of diverse etiologies results in chronic hyperglycemia and complications related to it. The earlier diagnosed the better complications prevented. Due to chronic nature of the disease, diabetics have to maintain a healthy life style that includes life style modification and healthy eating, keeping a control on amount of calories intake, depending on the type of diabetes a person is suffering with; principally diabetes mellitus is a metabolic disorder with variable clinical manifestations and progression. The longstanding hyperglycemia adversely affects multiple organ systems as heart, kidney, eyes and sensory nerves. Diabetic sensory neuropathy leads to burning sensation in soles of feet and paraesthesiae. The loss of sensation in feet's plays an important cause for the development of pressure sores which does not heal and ultimately terminating into diabetic gangrene. The development of gangrene forces the doctor to take drastic lifesaving steps as amputation, which makes the patient permanently immobile. Hence in diabetics, prevention and management of sensory neuropathy is of utmost importance. *Dhanyamla Dhara* and *Dashmoola kashaya Dhara* were used, which are considered as best *Vatakaphashamaka*, *Sothahara*, *Shoolahara* and *Balya* properties also will be effective in reducing major symptoms of Diabetic Neuropathy. Hence, these drugs are selected for the study to know their efficacy when used as DHARA in the Signs and Symptoms of Diabetic Sensory Neuropathy.

Materials and Methods:

Haritkyadi Yoga for Amapachana in both groups.

Ingredients: *Haritaki* – 1 part; *Amalki* – 1 part; *Vacha*– 1part; *Vidanga*– 1 part; *Haridra* – 1 part; *Shunthi* – 1 part; *Pippali* – 1 part; *Guda* – 1 part; *Lavana* – 1 part

Method of Preparation:

All the drugs were taken in completely dry form. Each drug was separately pounded and sieved (except *guda*); later the *Churnas* were mixed thoroughly in the equal quantity with *guda* and stored in airtight containers.

Dose – 5gm twice a day, **Anupana** – *Ushnodaka*,
Time of Administration – Before Food

Group A: *Dhanyamla (Chiktsa Manjari, Vaata Vyadhi):*

A total 360 liters of *Dhanyamla* was prepared in 3 batches at the department of *Rasashastra* and *Bhaishajya Kalpana*, A.M.V. Hubli.

Ingredients of *Dhanyamla*:

1. *Tandula* – 10 prastha quantity (7680 grams)
2. *Pruthuka* – 10 prastha quantity (7680 grams)
3. *Laja* – 40 pala quantity (1920 grams)
4. *Kulattha* – 40 pala quantity (1920 grams)
5. *Kangubeeja* – 01 adhaka quantity (3072 grams)
6. *Kodrava* – 04 prastha quantity (3072 grams)
7. *Nagara* – 2 prastha quantity (1536 grams)
8. *Nimbuka* – 2 adhaka quantity (6144 grams)
9. *Deepyaka* – Carom seeds – 8 kudava quantity (1536 grams)
10. *Jala* – 200 prastha (153.6 liters)

Method of Preparation:

A large deep vessel was placed on fire followed by pouring of 200 *prasthas* of water for boiling. Two *potlis* was prepared for convenience containing all drugs in appropriate quantity.

Then these *potlis* were hanged in vessel containing water with a rod placed over the vessel. Then pot was covered with a lid and was heated gently on a moderate fire for a period of 7 days.

The vessel was fumigated with *guggulu* etc. and proper preservation was done to made it devoid of microorganisms.

The temperature was not let to rised above the boiling point. Heating was continued for the next 7 days. From the 8th day onwards this liquid was used for *dhara* and the same quantity of boiled water was added into the vessel

Duration: 21 days

Usage: *Sarvanga Dhara* in Diabetic Sensory Neuropathy.

Group B: *Dashmoola Kashaya Dhara:*

Ingredients:

Brihat Panchamoola:

Bilva 1 Part; *Agnimantha* 1 Part; *Shyonak* 1 Part; *Patala* 1 Part; *Gambhari* 1 Part

Laghu Panchamoola: Shalaparni 1 Part, Prishniparni 1 Part, Brihati 1 Part, Kantakari 1 Part, Gokshur 1 Part.

Method of Preparation: 1 part of Dashmoola Kashaya churna and 8 part of water was taken in vessel and boiled until it reaches 1/4th of its part. Then it was filtered.

Duration: 21 days.

Usage: For Sarvangha Dhara.

Gandharva Hastadi Kashaya:

The kashayam was prepared by following herbs in equal parts. Gandharvahasta, Chirabilva, Hutasha, Vishwa, Pathya, Punarnava, Yavasa, Bhumitaala

• **Duration** : 21 days.

• **Dose** : 20- 40 ml at bedtime.

• **Usage** : For Nitya Virechana in both groups.

a) Source of data:

In this study the subjects attending the O.P.D & I.P.D of Department of Post-Graduate studies in Panchakarma, Ayurveda Mahavidyalaya and Hospital, Hubli.

b) Diagnostic Criteria:

A. Subjective Parameters:

1. History of Diabetes with any of the following signs and symptoms.

a. Burning Sensation (*Karapada Daha*) in Hands & legs.

b. Muscle weakness (*Dourbalya*) in Hands & legs.

c. Sensory loss (*Suptata*) in Hands & legs.

d. Symptoms worsens at night.

2. Physical examination:

a. Muscle strength and Reflexes.

B. Objective Parameters:

1. Vibration Test, Pin Prick,

2. Temperature Discrimination.

3. Hematological Examination including R/E, FBS, PPBS, LFT, RFT.

4. Electrophysiological Study (Nerve Conduction Study will be done to assess the condition of Nerves and to differentiate Axonal degeneration or demyelination type of Neuropathy. Test will be done BT and AT.

5. 'Glove – and – Stocking' impairment.

c) Inclusion criteria:

1. Subjects with either sex of age group between 30 to 50 years.

2. Subjects with clinical evidence of distal symmetrical Diabetic Polyneuropathy.

3. Subjects of controlled blood Sugar level with conventional medications.

d) Exclusion Criteria:

1. Patients with other metabolic and endocrine diseases.

2. Patients with autonomic, proximal and focal neuropathic state.

3. Patient suffering from infectious diseases.

4. Patients with wound/ulcer.

5. Patients with other complications like Diabetic Nephropathy, Diabetic Ketoacidosis and Diabetic Coma. Alcoholic Neuropathy/Drug Induced Neuropathy.

e) Study Design: - It is a randomized single blind comparative study with pre-test and post-test design.

f) Sample Size:- Totally 40 patients were selected to clinical trials. Patients were assigned into two groups.

1) Group A: In this group, 20 patients were treated with *Dhanyamla Dhara*.

2) Group B: In this group, 20 patients were treated with *Dashmoola Kashaya Dhara*.

h) Duration of treatment: For 21 days.

i) Parihara Kala : 42 days.

j) Follow Up : 3 months.

k) Statistical Analysis:

The analysis of the effects of therapy was based on "t-test" applications.

Observations:

1. Out of 40 patients, maximum 40 patients (100%) had *Karpada Daha* and Symptoms worsens at Night, 38 patients (95.00%) had *Suptata* and 15 patients (37.50%) had *Dourbalya*.

2. Out of 40 patients, maximum 20 patients (50%) had Reduced Reflexes and 15 patients (37.50%) had Reduced Muscle Strength.

3. Out of 40 patients, maximum of 35 patients (87.5%) had Light Touch Loss, Temperature

- sensation Loss, Vibration Loss, Position Change Loss and Pain Sensation Loss.
- Out of 40 patients, maximum of 32 patients (80.00%) had Neuropathy, 08 patients (20.00%) had Mild- Neuropathy.
 - Out of 40 patients, maximum of 40 patients (100%) had Stocking Impairment, 11 patients (47.5%) had Glove and Stocking Impairment.

Results:

Table 1:

Subjective Parameters	Percentage of Relief	
	Group A	Group B
Karapada Daha	75.00	73.58
Dourbalya	78.57	68.75
Suptata	76.00	71.43
Symptoms Worsens at Night	85.71	72.55

Table 2:

Objective Parameters	Percentage of Relief	
	Group A	Group B
Muscle Strength	70.00	60.78
Reflexes	70.00	64.00
Light Touch	75.86	67.86
Temperature	78.26	68.00
Vibration	63.16	52.38
Position Change	75.00	63.64
Pain	76.00	65.38
NCS	17.14	13.51
Stocking	75.00	60.00
Glove and Stocking	70.00	58.33

The therapy under Group A provided Marked Improvement for 13 subjects and Moderate improvement for 07 subjects. The therapy under Group B provided Marked Improvement for 09 subjects, Moderate improvement for 08 subjects and Mild Improvement for 03 subjects.

DISCUSSION

- DSN is *upadrava* of *Madhumeha*, which is one type of *vataja prameha*. So, the main involved *dosha* in this condition is *Vata dosha* along with *Pitta* and *Kapha*. In *Ayurveda lakshanas* like *Pada suptata*, *Padaharsha* are dealt under *vatavyadhis*. And *Daha* is explained as a separate disease under *Pitta Vyadhi*. In which one type of *daha* is *Dhatukshayaj Daha*, which is due to *avarana of Vata*; same *daha* is seen in DSN.
- Main involvement in the pathophysiology of DSN is due to *tridoshas* mainly *Vata* and *Kapha*; as the symptoms like *Karapada Daha* which may be due to *prakupita vata* along with *pitta*, *Karpada Suptata* due to *prakupita vata* and *kapha*, *Dourbalya* may be due to *prakupit Vata*.
- As main vitiated *doshas* are *vata* and *Kapha* and *Dhanyamla* and *Dashmoola* both possess *Vata hara* and *Kapha hara* properties. So, this might be the reason for decrease in the Signs and Symptoms and providing relief to the patients of DSN.

Discussion on Probable mode of action of Dhanyamla Dhara:

- *Amla rasa* – According to *Ayurveda* kindles the *agni* and acts as *deepana* and gets rid of *ama* (endotoxins formed due to errors of metabolism) and acts as *pachana*. Since many diseases are manifested because of bad metabolism, *Dhanyamla dhara* de-roots these diseases from base. Thus, *Dhanyamla dhara* forms the first line of treatment in many systemic disorders having their origin from weak digestion or errors of metabolism.
- Apart from this, *Amla Rasa* is *Hridya*, *Rochana*, *Laghu* and *Snigdha*. The digestive power of *agni* or core fire in the body will get enhanced due to the impact of *Laghu* and *Teekshna Guna's* of *Dhanyamla*.
- Due to its *Ushna Guna* and *Ushna Veerya*, *Dhanyamla* destroys the vitiated *Vata* or *Kapha* or *Vata-Kapha*. The same properties make *Dhanyamla* antagonistic to *ama* and *Meda*.
- With the help of these properties *Dhanyamla* removes the blocks in the cells and channels of transportation and nutrition. The cells will start getting proper nutrition and building elements, which in turn enhances the strength and immunity of the body. *Dhanyamla* is thus highly effective in *ama* disorders, *Vata* disorders, *Kapha* disorders and *Vata-Kaphaja* Disorders.
- Owing to its properties of *Vatanulomana*, *Shula prashamana*, *Nadi uttejaka*, *Vedana sthapana*, *Dhanyamla* effectively combats *Vata* and *Vata* disorders.

Discussion on Probable Mode of Action on Dashmoola Kashaya Dhara

1. Increases metabolic rate: By *Swedana* process, our body temperature is increased and due to increase in body temperature, sympathetic activities are also increased. Because of increased Sympathetic activities hormones like Epinephrine, Norepinephrine, Cortisol, Thyroid Hormones are released which accelerate the metabolic rate and stimulate the process of lipolysis. As a result of increased metabolism there is increased

demand for oxygen and increased output of waste products. It can be correlated with digestion of *Ama*.

2. Vasodilatation: If the body temperature rises a negative feedback action becomes active to reach at normal temperature. Higher temperature of the blood stimulates thermo receptors that send nerve impulses to the preoptic area of the brain. Which in turn stimulate the heat losing center and inhibit the heat promoting center. Nerve impulses from the heat losing center cause dilation of blood vessels in the skin so the excess heat is lost.

3. Stimulation of Sweat Glands: A high temperature of blood stimulates sweat glands of the skin via hypothermic activation of sympathetic nerves and by this procedure excessive sweat production takes place. With the increased Sweat production more waste products are expelled Out of the body through the medium of sweat. Hence, it can be said that *Swedana* corrects *Swedavah-Sroto-dushti*.

CONCLUSION

The Symptoms mentioned in our Classical texts as mentioned under *Upadrava* of *Prameha* such as *pada daha*, *pada suptata*, and *Dourbalaya* are like Diabetic Sensory Neuropathy Signs and Symptoms. Diabetic Sensory Neuropathy can be treated as *Upadrava* of *Prameha* as explained in our Classics. The pathology behind the Neuropathy is damage of the blood vessels supplying nerve fibres secondary to the presence of excessive amount of glucose. This patho-physiology of the diabetic peripheral neuropathy is collectively called as microangiopathy. The poor or no supply of nutrients to the nerve fibres by blood vessels causes the damage to the nerve anatomy and physiology and tends to cause pathology showing symptoms as burning, tingling, pricking, numbness and loss of sensation of touch etc. By this we can conclude that this may be due to *avarana* of *Vata* by *kapha* and *pitta*. *Dhanyamla* which is rich in phyto-chemicals like flavonoids and tannins which promote healing process by increasing formation of capillaries and hence it can be concluded that it can be helpful in providing nutrients to nerve fibers and can be helpful in treating Signs and symptoms Diabetic Sensory

Neuropathy. Antioxidant and anti-toxic actions of *Dhanyamla* will help in reducing the progression of Diabetic Sensory Neuropathy. *Dashmoola Kashaya* when poured over body stimulates metabolism, Vasodilation and Sweat glands which ultimately have an impact on Nervous System and Endocrine System and hence it will help in treating Diabetic Sensory Neuropathy. *Dashmoola Kashaya* being *Tridoshahara* mainly *Vata* and *Kapha* have major role to subside the signs and symptoms of Diabetic Sensory Neuropathy. But if we see the difference in average percentage of relief i.e. (7.42) between *Dhanyamla Dhara* and *Dashmoola Kashaya Dhara*; another conclusion can be drawn as *Parisheka Sweda* with *Vata Kapha Shamak* drugs are effective in Degenerative Disorders like Diabetic Sensory Neuropathy. So, from this it can be concluded that *Sarvanga Dhara* for longer duration i.e. 28 days can give more effective results.

Recommendations for the further study:

1. As the study was done on small sample size however for more accurate result, large sample study for longer period may be conducted.
2. Studies to describe the effect of *Sarvanga Dhara* on regeneration of Myelin Sheath with modern techniques.

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