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A clinical study to evaluate the combined effect of *Kanjikataila Sthanika Abhyanga, Dhanyamla Parisheka* and *Paripathadi Kadha* in the management of *Prameha Upadrava* vis-à-vis Diabetic Peripheral Neuropathy [DPN]

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ABSTRACT

The commonest form of complication of Diabetes Mellitus is Diabetic Peripheral Neuropathy [DPN] and is estimated to effect half of the population with diabetes mellitus. The reported worldwide prevalence of Diabetic Peripheral Neuropathy ranges from 16% to as high as 66%. Symptoms of Diabetic Peripheral Neuropathy [DPN] include sharpness or burning pain that begins in feet and spreads proximally, sensation of numbness and tingling sensation. These features resemble the features of *Prameha Upadrava* which are *Daha, Nidranasha, Paridhoopana, Shoola, Toda*, and *Harsha* along with symptoms of *Prameha.* DPN represents a major health problem as it may present with excruciating neuropathic pain and responsible for substantial morbidity, impairs quality of life, and increases mortality. Present study is a single group open clinical trial with pre-post-test design with sample size of 30 subjects. Intervention to subjects of DPN was *Kanjika Taila Sthanika Abhyanga* followed by *Dhanyamla Parisheka* to the affected limbs for the first 10 consecutive days with internal administration of *Shamanoushadhi* for all 30 consecutive days. The result obtained on the parameters of the LANSS scale was statistically highly significant with 'p' value 0.000 in the management of *Prameha Upadrava* vis~a~vis DPN.

Key words: *Prameha Upadrava, Sthanika Abhyanga, Parisheka, Diabetic Peripheral Neuropathy*

INTRODUCTION

Diabetic neuropathy is defined as a demonstrable disorder, either clinically evident or subclinical, that occurs in the setting of diabetes without other causes for peripheral neuropathy.[1] The yearly incidence of distal symmetric polyneuropathy in diabetics is approximately 2%, and the lifetime incidence of neuropathy has been estimated to be 37% - 45% for patients with type 2 DM and 54 % - 59% for patients with type 1 DM. Recent guidelines published by American Diabetes Association identify patients at high risk for future diabetes as those with a glycosylated haemoglobin of 5.7% - 6.4% as well as patients with impaired fasting glucose (IFG) – fasting plasma glucose of 100mg/dL to 125mg/dL – and impaired glucose tolerance (IGT), a 2-hour oral glucose tolerance test value of 140 mg/dL to 199mg/dL.[2]

Diabetic Peripheral Neuropathy is one of the complications *(Upadrava)* of Diabetes Mellitus. *Upadrava* are those which develop after the onset of main disease and is dependent on the main disease. The *Upadrava* will have the *Samprapti* of its own and needs specific intervention. In *Prameha Upadrava*, as the disease *Prameha* progress and due to further intake of aetiological factors, *Vata Dosha* will be aggravated and is the cause for the development of

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Prameha Upadrava. The main presenting complaint of DPN is burning sensation and the prime *Dosha* involved is *Vata* along with *Pitta*. Considering these, medicaments which acts as *Daha Shamaka* and *Vata-Pitta Hara* were selected.

As *Dahashamaka*, *Kajika Taila Sthanika Abhyanga* and *Dhanyamla Parisheka*, as *Vata-Pitta Hara, Paripathadi Kadha* has been selected in the management of *Prameha Upadrava* vis-à-vis DPN.

OBJECTIVE OF THE STUDY

Objective of the present study was to evaluate the combined effect of *Kanjika Taila Sthanika Abhyanga, Dhanyamla Parisheka* and *Paripathadi Kada* in the management of *Prameha Uapadrava* via-a-vis Diabetic Peripheral Neuropathy.

METHODS

Source of Data

Subjects were selected from the O.P.D. and I.P.D. of Government Ayurveda Medical College and Hospital, Mysore and Hi-tech Panchakarma Hospital, a teaching Hospital of Government Ayurveda Medical College, Mysore.

Sample Size - 30 Subjects

Inclusion Criteria

- Subjects of all gender between the age group of 18-70 years were included.
- Subjects with both Type-1 Diabetes mellitus and Type-2 Diabetes mellitus, with peripheral neuropathy were included.

Exclusion Criteria

- Subjects with other complications of diabetes mellitus like diabetic nephropathy, infectious wounds, gangrene and foot ulcers were excluded.
- Subjects with uncontrolled diabetes mellitus i.e., FBS>300mg/dL and PPBS>350mg/dL were excluded.
- Subjects of hypertension having blood pressure of >160/100mmHg were excluded.
- Subjects with metabolic disorders & systemic disorders which interfere with the intervention were excluded.
- Subjects unfit for *Sthanika Abhyanga* and *Parisheka* were excluded.
- Pregnant and lactating women were excluded.

Diagnostic Criteria

Diabetic Neuropathy Symptom Score scale (Annexure 1) was use to diagnose DPN.

Assessment

Assessment schedule

In this study, total 3 assessments were done.

1. Pre-test assessment - Before starting the intervention (0^{th} day)
2. Mid test assessment – After the completion of *Sthanika Abhyanga* and *Parisheka* (11^{th} day)
3. Post-test assessment - After the completion of total intervention (31^{st} day)

Assessment criteria (Annexure 2)

The Leeds Assessment of Neuropathic Symptoms and Signs Pain scale (LANSS) was used to assess the signs and symptoms of DPN before and after the intervention.

Statistical Methods

The data obtained were analysed statistically by applying Descriptive statistics, Paired sample t test, Chi square test statistical methods and results are analysed using SSPS windows.

Intervention

The interventions were as follows:

- *Kanjika Taila*[3] *Sthanika Abhyanga* for 15 minutes followed by *Dhanyamla*[4] *Parisheka* to the affected limb for 30 minutes for the first 10 consecutive days of intervention.
- Internal administration of 50ml of *Paripathadi Kadha* [5] in two equally divided doses during morning and night before food for 30 consecutive days of intervention.

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Total duration of intervention - 30 days.

RESULTS

Result on pins and needle sensation (questionnaire 1)

Out of 30 subjects, before intervention 13 (43.3%) had very severe pins and needle sensation, 9 (30.0%) had severe pins and needle sensation, 6 (20.0%) had moderate pins and needle sensation and 2 (6.7%) had mild pins and needle sensation.

During intervention i.e., on 11th day, 3 (10.0%) subjects had severe pins and needle sensation, 11 (36.7%) had moderate pins and needle sensation, 10 (33.3%) had mild pins and needle sensation, 4 (13.3%) had very mild pins and needle sensation and 2 (6.7%) had no pins and needle sensation.

After the completion of intervention, i.e., on 31st day, 2 (6.7%) had severe pins and needle sensation, 2 (6.7%) had moderate pins and needle sensation, 7 (23.3%) had mild pins and needle sensation, 11 (36.7%) had very mild pins and needle sensation and 8 (26.7%) had no pins and needle sensation.

The result obtained regarding the questionnaire 1 showed statistically highly significant result with 'P' value of 0.001.

Result on change in skin colour (questionnaire 2)

Out of 30 subjects, before intervention 30 (100.0%) did not presented with change in skin colour in painful area.

During intervention i.e., on 11th day, 30 (100.0%) did not presented with change in skin colour in painful area.

After the completion of intervention, i.e., on 31st day, 30 (100.0%) did not presented with change in skin colour in painful area.

The result obtained regarding the questionnaire 2 showed statistically insignificant result.

Result on hyperesthesia (questionnaire 3)

Out of 30 subjects, before intervention 12 (40.0%) had hyperaesthesia in bilateral soles/palms, 10(33.3%) had moderate hyperaesthesia in bilateral soles/palms, 1 (3.3%) mild hyperaesthesia in bilateral soles/palms and 7 (23.3%) had no hyperaesthesia in bilateral soles/palms.

During intervention i.e., on 11th day, 6 (20.0%) had moderate hyperaesthesia in bilateral soles/palms, 11(36.7%) had mild hyperaesthesia in bilateral soles/palms and 13 (43.3%) had no hyperaesthesia in bilateral soles/palms.

After the completion of intervention, i.e., on 31st day, 3 (10.0%) had moderate hyperaesthesia in bilateral soles/palms, 6 (20.0%) had mild hyperaesthesia in bilateral soles/palms and 21 (70.0%) had no hyperaesthesia in bilateral soles/palms.

The result obtained regarding the questionnaire 3 showed statistically highly significant result with 'P' value of 0 .001.

Result on electric shock like sensation (questionnaire 4)

Out of 30 subjects, before intervention 19 (63.3%) had repeated episodes of electric shock like sensation, 6 (20.0%) had less frequent episodes of electric shock like sensation, 5 (16.7%) had no episodes of electric shock like sensation.

During intervention i.e., on 11th day, 5 (16.7%) had repeated episodes of electric shock like sensation, 14 (46.7%) had less frequent episodes of electric shock like sensation, 11 (36.7%) had no episodes of electric shock like sensation.

After the completion of intervention, i.e., on 31st day, 1 (3.3%) had repeated episodes of electric shock like sensation, 12 (40.0%) had less frequent episodes of electric shock like sensation, 17 (56.7%) had no episodes of electric shock like sensation.

The result obtained regarding the questionnaire 4 showed statistically highly significant result with 'P' value of 0 .001

Result on burning sensation (questionnaire 5)

Out of 30 subjects, before intervention 29 (96.7%) had burning sensation in bilateral soles/ palms, 1(3.3%) had no burning sensation in bilateral soles/ palms.

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During intervention i.e., on 11th day, 18 (60.0%) had burning sensation in bilateral soles/ palms, 12 (40.0%) had no burning sensation in bilateral soles/ palms.

After the completion of intervention, i.e., on 31st day, 5 (16.7%) had burning sensation in bilateral soles/ palms, 25 (83.3%) had no burning sensation in bilateral soles/ palms.

The result obtained regarding the questionnaire 5 showed statistically highly significant result with 'P' value of 0 .001

Result on allodynia (questionnaire 6)

Out of 30 subjects, before intervention 12 (40.0%) had very severe allodynia in bilateral soles/ palms, 10 (33.3%) had severe allodynia in bilateral soles/ palms, 5 (16.7%) had moderate allodynia in bilateral soles/ palms, 1 (3.3%) had mild allodynia in bilateral soles/ palms and 2 (6.7%) subjects had no allodynia in bilateral soles/ palms.

During intervention i.e., on 11th day, 4 (13.3%) had severe allodynia in bilateral soles/ palms, 10 (33.3%) had moderate allodynia in bilateral soles/ palms, 12 (40.0%) had mild allodynia in bilateral soles/ palms, 1 (3.3%) subject had very allodynia in bilateral soles/ palms and 3 (10.0%) had no allodynia in bilateral soles/ palms.

After the completion of intervention, i.e., on 31st day, 1 (3.3%) had severe allodynia in bilateral soles/ palms, 2 (6.7%) had moderate allodynia in bilateral soles/ palms, 10 (33.3%) had mild allodynia in bilateral soles/ palms, 7 (23.3%) subjects had very allodynia in bilateral soles/ palms and 10 (33.3%) had no allodynia in bilateral soles/ palms.

The result obtained regarding the questionnaire 6 showed statistically highly significant result with 'P' value of 0 .001

Result on altered pin prick threshold (questionnaire 7)

Out of 30 subjects, before intervention 20 (66.7%) subjects had raised pin prick threshold in bilateral soles/ palms, 9 (30.0%) had altered pin prick threshold in bilateral soles/ palms and 1 (3.3%) subject had lowered pin prick threshold in bilateral soles/ palms.

During intervention i.e., on 11th day, 3 (10.0%) subjects had raised pin prick threshold in bilateral soles/ palms, 8 (26.7%) had altered pin prick threshold in bilateral soles/ palms, 17 (56.7%) subjects had lowered pin prick threshold in bilateral soles/ palms and 2 (6.7%) subjects had equal sensation in both the areas of bilateral soles/ palms.

After the completion of intervention, i.e., on 31st day, 5 (16.7%) had altered pin prick threshold in bilateral soles/ palms, 16 (53.3%) subjects had lowered pin prick threshold in bilateral soles/ palms and 9 (30.0%) subjects had equal sensation in both the areas of bilateral soles/ palms.

The result obtained regarding the questionnaire 7 showed statistically highly significant result with 'P' value of 0 .001.

Discussion

In *Prameha Upadrava* vis~a~vis DPN, there is *Vata Pradhana Tridosha* vitiation in the pathophysiology. Vitiated *Vata Dosha* alone causes *Shoola, Toda, Anga Shosha* and *Spandana*. Vitiated *Vata Dosha* in association with vitiated *Pitta* and *Rakta* cause *Daha. Vata Dosha* and *Kapha Dosha* are responsible for *Harsha*. In *Charaka Samhita, Visarpa Adhyaya* – while explaining *Upadrava*, *Chakrapani* commentator of *Charaka Samhita* states that, the diseases manifested in the form of complications will subside after treating the main disease. But some *Upadrava* may require *Swatantra Chikitsa* which needs to be managed independently and immediately.[6] As DPN is one such *Upadrava* with *Vata Dosha* predominance, it needs separate intervention.

Among the general *Chikitsa Sutra* mentioned in *Vata Vyadhi*, *Bahya Snehana* and *Swedana* are suitable. *Bahya Snehana*, in the form of *Abhyanga, Padabhyanga* and based on the condition of patient, *Swedana* in the form of *Parisheka Sweda* are beneficial in DPN. *Abhyanga* is *Twachya* and does *Prashamana* of *Vata* because *Spanrshanendriya* is one of *Adhishtana* of *Vata*.[7] *Abhyanga* also improves *Balakarma* which means it may help in proper functioning of *Vatavaha*

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Sira. In specific, *Pada Abhyanga* reduces *Supti, Shrama* and prevents *Sira Sankocha*.[8]

In this study *Kanjika Taila* for *Sthanika Abhyanga* was selected based on its indication in *Daha* (burning sensation). Trans dermal absorption depends upon lipid solubility of the drug. Drug in oils and other lipids soluble carriers can penetrate the epidermis as it is a lipid barrier. By the process of rubbing, the active principles of the drug dissolves through stratum corneum without molecular dispersion and gets diffused through the barrier. These procedures will work on nervous system, increase the blood circulation, affects the lymphatic system to facilitate removal of toxins from the tissue and supplies more nourishment to the blood. *Parisheka Sweda* is one among *Snigdha, Sagni* and *Drava Sweda*. It is said to be *Vata Kapha Hara*[9] and *Vata Pitta Hara*.[10] *Dhanyamla* is *Jeevana* as it is prepared from different variety of *Dhanya*. On *Sparsha* it is *Daha Nashaka* and also acts as *Vata Kaphahara*. Pouring the tepid medicated liquid stimulates the local receptors and hypothalamus which in turn causes sympathetic stimulation and adrenalin secretion leading to adipose lipolysis and generation of sweat. The tepidness of the liquid dilates the capillaries which increases the circulation, elimination of waste products and more absorption of oil-based medicines through skin.

Total benefit of these *Bahya Chikitsa* is - it reduces *Shoola, Toda, Ruja* and brings *Pushti* to affected parts.

Paripathadi Kadha can be considered to have *Katu, Tikta* and *Kashaya Rasa, Sheeta Veerya* and *Tridosha Hara Karma*. Its main indication is in *Daha* of different aetiology and it can be substantiated as majority of drugs have both anti-neuropathy and anti-diabetic activities.

Ingredients	Actions
Parpata / Paripatha	Neuroprotectant, anti-oxidant and analgesic activities.[11]
Indrayava	Reduces neuropathic pain through modulation of oxidative–nitrosative stress.[12]
Bhunimba	Peripheral and central antinociceptive activity. Aqueous extract of Swetia chirata has anti-diabetic activities.[13]
Guduchi	Prevents the hyperalgesia in diabetic neuropathy.[14]
Musta	Hydrolic extract of *Musta* has anti neurologic effect and hyperalgesia.[15]
Shunti	Antioxidant effect and improves neuropathy and axon density in diabetes.[16]

Statistical results on parameters of the LANSS scale like pins and needle sensation, burning sensation, hyperesthesia, electric shock like sensations, allodynia and pin prick threshold showed highly significant result at the end of intervention with P value of 0.001. The combination of *Kanjika Taila Sthanika Abhyanga, Dhanyamla Parisheka* and *Paripathadi Kadha* are found to be effective in management of Diabetic Peripheral neuropathy.

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