

## AN OPEN LABEL RANDOMIZED COMPARATIVE STUDY ON SARVANGA TAKRADHARA AGAINST SIRO TAKRADHARA IN DIABETIC PERIPHERAL NEUROPATHY (DPN)

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### ABSTRACT

**Background:** There are indications for *takradhara* over head and body in diseases like *Prameha* and its complications. But the difference between the effect of *takradhara* over head and body is unknown. Hence the present study has been taken to compare the effect of *Sarvanga takradhara* and *Siro takradhara* in Diabetic Peripheral neuropathy (DPN). **Objectives:** To study the effect of *Sarvanga takradhara*, *Siro takradhara* and compare their efficacy in DPN. **Methods:** Twenty Participants satisfying the eligibility criteria were selected from OPD of VPSV Ayurveda College Hospital, Kottakkal and allocated into two groups (Group A & B), which received *Sarvanga takradhara* and *Siro takradhara* respectively. The subjective and objective assessments were done. Efficacy was assessed on Neuropathy Impairment Score (NIS), Visual Analogue Scale (VAS), symptoms of DPN, QoL and blood parameters. **Results & Discussion:** There was significant reduction observed in NIS score, VAS, symptoms & QoL in both groups ( $P < 0.05$ ). *Siro takradhara* showed significant reduction in blood sugar level (FBS and PPBS). **Conclusion:** Both *Sarvanga takradhara* and *Siro takradhara* were effective in reducing the signs and symptoms of diabetic peripheral neuropathy.

**Keywords:** *Sarvanga takradhara*, *Siro takradhara*, Diabetic Peripheral Neuropathy

### INTRODUCTION

*Takradhara* is a procedure, where medicated butter milk is poured over head or body in a specified manner<sup>1,2</sup>. Previous research works show that it gives good results in stress related lifestyle disorders like Hypertension<sup>3</sup>, Diabetes mellitus<sup>4</sup>, Psoriasis<sup>5</sup> & other Psychosomatic diseases etc. *Takradhara*, when it is done over the head is known as *Siro takradhara*,<sup>6</sup> whereas the procedure done on the body is named as *Sarvanga*

*takradhara*<sup>7</sup>. There is an indication for *Siro takradhara* in *Jwara*, *Sarvangatakradhara* in *Kushta* where as both are indicated in *Prameha*<sup>8,9</sup>. It is unknown that why a particular procedure is indicated over two areas viz head and body in the same disease and what is the difference between the effects of two methods. Hence the present study has been designed to compare the

effect of *Sarvangatakradhara* and *Sirotakradhara* in DPN.

Diabetic Peripheral Neuropathy (DPN) is the Presence of symptoms/signs of peripheral nerve dysfunction in Diabetes mellitus people after exclusion of other causes. This can present with symptoms varying from numbness, paraesthesia (pins and needles) to burning, sharp and shooting pains<sup>10,11</sup>. In *Ayurveda* the *Achar-yas* have invariably given detailed description of *prameha*, its causes, types, pathology and the line of treatment. The features such as *Kara Pada daaha*<sup>12,13</sup>(burning sensation), *Cimcimayana* (tingling sensation), *Suptata* (numbness), *todam* (Pricking pain) are symptoms seen in *Prameha rogi* either in prodromal stage or in the actual exhibition stage or in complication stage, which is identified as Diabetic peripheral neuropathy.

#### Objectives

- To study the effect of *Sarvanga takradhara* in the management of Diabetic Peripheral Neuropathy.
- To study the effect of *S'iro takradhara* in the management of Diabetic Peripheral Neuropathy.
- To compare the efficacy of *Sarvanga takradhara* against *S'iro takradhara* in Diabetic Peripheral Neuropathy

#### Methodology:

**Materials:** *Aamalaki kwatha*, *Mustha churna*, *Balaguloochyadi tailam*, *Rasnadi churna*, Milk & Curd.

Fresh samples of *all medicines* were purchased from a reputed medical store. **Accessories:** Two large steel vessels, mixie, gas stove, Digital weighing machine, *Dharapathy*, *Dhara* stand, *Dhara* pot, Michigan Neuropathic Screening Instrument, Neuropen, Tuning fork-128, Cotton, cloth etc.

**Ethical committee clearance:** After various level of scrutiny, the whole plan of the study (IEC /CL/18/14 dated on 27/05/2014) was approved by Institutional Ethics Committee (IEC) of VPSV Ayurveda College, Kottakkal, Consent form in Malayalam language was prepared and prior consent of all participants were obtained.

**Selection of participants:** 20 Participants who attended the OPD of *Pancakarma*, VPSV Ayurveda college Hospital, Kottakkal during the study period satisfying the eligibility criteria were selected and admitted them in IPD. Participants selected were randomly allocated in to two groups (Trial group and control group) consisting of 10 participants in each group based on Random number table method.

**Study Design:** Comparative Clinical Trial

**Sample size:** 20

**Study Setting:** IPD of VPSV Ayurveda College Hospital Kottakkal

**Study Duration:** 18 months

**Table 1:** Group allocation

Group	No. of participants Registered	Treatment given	No. of participants Completed	Dropouts
A	10	<i>Sarvanga takradhara</i>	8	2
B	10	<i>S'iro takradhara</i>	10	0

There were 2 dropouts in the *Sarvanga takradhara* group because,

- 1- Due to development of some ulcers in the body on 10<sup>th</sup> day.
- 2- Due to increase of pain in 7<sup>th</sup> day.

#### Diagnostic criteria:

- H/o Hyperglycemia
- Michigan Neuropathic Screening Instrument<sup>15</sup>: Questionnaire Part  $\geq 7$ +ve or Examination part  $\geq 2$  +ve

#### Inclusion criteria:

1. Fulfill diagnostic criteria of Diabetic Peripheral neuropathy
2. Type-2 diabetes with/without receiving anti diabetic medication
3. 30 -70 yrs age group.
4. Both sex.
5. Eligible for *Takradhaara*
6. Participants who have given informed consent.

**Exclusion Criteria:**

1. Patients suffering from: Type 1 DM, Gestational DM
2. Known cases of other Endocrine disorders, Malignancy, Liver disorders
3. Patients with infectious diseases
4. Patients suffering from foot ulcer/amputation
5. Pregnant and lactating women.

**Withdrawal Criteria:**

1. Participants develop any serious adverse effects during procedure.
2. Noncompliance of the participant with *Takradhara* procedure and regimen.

**Assessment Criteria:**

- Sensory functions: Neuropathy Impairment Score<sup>16</sup>
- Motor functions: Muscle power, Muscle tone, Muscle Bulk
- Quality of Life (QoL): Neuro Qol<sup>17</sup>
- Pain: Visual Analogue Scale
- Monofilament test (assessment of fine touch sensation using Neuropen with Semmes Weinstein monofilament, which can apply 10g force)

- Vibration perception test (Using 128Hz tuning fork)
- Symptom scoring Based on *Ayurvedic* symptomatology: *Karapadadaha* (Burning sensation), *Chimicimayana* (Tingling sensation), *Suptata* (Numbness), *Todam* (Pricking Pain)
- Lab Investigation: Blood Routine, FBS, PPBS

The whole parameters were assessed both before and after treatment.

**Intervention:** Preparation of *Takra* and the procedure of *Takradhara* were done according to the description available in “*Dhara kalpa*”.

- *Poorva Karma* – *Abhyangam* with *Balaguloochyadi Tailam* (both head and body).
- *Pradhana Karma –Takradhara* (According to Standard Operative Procedure)<sup>18</sup>, published by Department of Panchakarma, VPSV Ayurveda College, Kottakkal.
- *Paschat Karma:* Wash with *Aamalaki Kwatham*, Apply *Rasnadi Choornam* on head, Rest for 1 hour and hot water bath

**Table 2:** Intervention of the study

Particulars	Group A	Group B
Sample size	10	10
Procedure	<i>Sarvanga Takradhara</i>	<i>S'iro Takradhara</i>
Quantity	3 L	3 L
Time duration	35 mt.	35 mt.
Time	3-4 pm	3-4 pm
Days	14	14

**Method of Preparation of *Takra*:** 1.5L of milk, diluted with equal quantity (1.5 L) of water. 100gm of *Mustha* was tied in a muslin bag and put into this diluted milk, boiled and reduced to original quantity of milk, i.e. 1.5 L. After cooling, little quantity of curd was added and kept overnight to get fermented. Next day morning fermented curd was churned well by adding *Aamalaki kwatha*.

**Method of Preparation of *Aamalaki Kwatha*:** 200 gm of *Aamalaki* was boiled in 6 liters of water & reduced to 3 liters, filtered and collected in a vessel.

From this 1.5 liter of *kwatha* mixed along with the *Takra* and rest 1.5 L used for wash after *dhaara*.

**Collection of Data & Data Analysis:**

For collecting the data of participants, a case record form (CRF) was prepared to record all the possible demographic data along with relevant clinical findings and lab investigation values from each group both before and after treatment. All the data were tabulated and subjected to statistical analysis manually with the help of excel sheet, SPSS software & Graph Pad Instat version 3.10. Q-Q plots were drawn in order to test whether the data were normally distributed. If it fol-

lows normality, parametric test was done and those data which does not follows normality, non-parametric tests were done. The effect of therapy within the groups were analyzed using paired ‘t’ test and Wilcoxon matched pairs signed rank test. The effect of therapy between the groups were analyzed by unpaired ‘t’ test and Mann Whitney test.

**Observation and Analysis:**

**1.Effect of therapy on NIS:**

NIS includes assessment of touch pressure, vibration sense, joint position sense, pinprick sense, reflexes and muscle weakness. For touch sensation, Group A (*sarvanga takradhara*) showed improvement of 23% (p< 0.05) and group B (*shiro takradhara*) was 5% (p<0.05). For pinprick sensation, Group A showed improvement of 20 % (p<0.05) and group B showed improvement of 5% (p<0.05). Improvement of both sensations were insignificant (p>0.05) while comparing between groups.

**Table 3:** Effect on sensation

Touch pressure	Mean		W-rank	p value
Group A	1.9 (BT)	1.5(AT)	T+=10; T-=0	p<0.05
Group B	1.6(BT)	1.5 (AT)	T+=1; T-=0	p<0.05
Comparison	0.4(Group A)	0.1(Group B)	U static=35	p>0.05
Pinprick				
Group A	1.8(BT)	1.5(AT)	T+=6; T-=0	p<0.05
Group B	1.6(BT)	1.5 (AT)	T+=1; T-=0	p<0.05
Comparison	0.3(Group A)	0.1(Group B)	U static=40	p>0.05

The mean score vibration, both before & after treatment were 2.1 in both groups. On analyzing this value, there was no change in vibration obtained in both groups after *takradhara*. In this study all the participants of both groups were affected, i.e. diminished vibration sense (Vibration with 128Hz tuning fork can feel<10 sec). In both groups, clinically some improvement for vibration sensation were noted. But both groups showed statistically “no change”. This may be due to some problems related to assessment with NIS tool, i.e. vibration sense graded as>10 sec (normal),1-9 sec (diminished) and 0 sec (absent). Even though some improvement in vibration sense occurred (Eg;4sec before treatment, improved as 8sec after treatment), the grading remains same as “diminished”. So, no change was observed.

For **joint position sense**, all the participants of both groups were presented as normal. For **Reflexes**, all the participants except one participant were presented with normal reflexes. Only one patient had diminished reflexes. But that case was drop out. For **Motor Functions**, all the participants were presented with normal muscle bulk, normal muscle tone and normal muscle

power. Hence there was “no change” observed in these assessments after treatment.

**2.Effect of therapy on Monofilament test:** In this study all the participants of both groups were affected with diminished sensation (fine touch sensation can feel<10 times). In both Groups clinically some improvement was noted after *takradhara*. But both groups showed statistically “no change”. This may be due to some problems related to assessment with monofilament test.i.e; fine touch sensation graded as, if the patient feel touch with monofilament>10 times (normal), 1-9 times (diminished) and 0 times (absent). Even though some improvement in fine touch occurred (E.g. 4times before treatment improved as 8times after treatment), the grading remains same as “diminished”. Mean value noted as 2.1 both before & after treatment in both groups. So statistically “no change” was observed.

**3.Effect of therapy on VAS:** Pain is the main symptom present in DPN. In this study, pain presented in all participants & all had a VAS score 5 or above. For VAS, in Group A reduction of 50% (p<0.001) was noted and in group B reduction of 58% (p<0.001) was

noted. Improvement of VAS was insignificant ( $p>0.05$ ) while comparing between groups. So, both *takradhara* were equally effective in reducing VAS.

**4.Effect of therapy on QoL:** In Group A improvement of 16% ( $p<0.01$ ) was noted and in group B im-

provement of 21% ( $p<0.01$ ) was noted. Improvement in QoL was insignificant ( $p>0.05$ ) while comparing between groups.

**Table 4:** Effect on VAS & QoL

VAS	Mean		t value	p value
Group A	5.9 (BT)	3 (AT)	4.52	$p<0.001$
Group B	5.8(BT)	2.4 (AT)	7.51	$p<0.001$
Comparison	2.9(Group A)	3.4(Group B)	0.63	$p>0.05$

  

QoL	Mean		t value	p value
Group A	64.4 (BT)	75.3 (AT)	3.9	$P<0.01$
Group B	71.5 (BT)	83.9 (AT)	4.1	$P<0.01$
Comparison	12.4 (Group A)	10.9 (Group B)	5.68	$p>0.05$

**5.Effect of therapy on symptoms:**

**Chimichimayana (Tingling sensation):** In Group A reduction of 60% ( $p<0.05$ ) and in group B reduction of 46% ( $p<0.05$ ) were noted. This reduction was insignificant ( $p>0.05$ ) while comparing between groups.

**Supthi (Numbness):** In Group A reduction of 35% ( $p<0.01$ ) and in group B reduction of 58% ( $p<0.01$ ) were noted. This reduction was insignificant ( $p>0.05$ ) while comparing between groups.

**Karapada Daha (Burning sensation):** In Group A reduction of 65% ( $p<0.001$ ) was noted and in group B reduction of 90% ( $p<0.001$ ) was noted. This reduction was insignificant ( $p>0.05$ ) while comparing between groups.

**Todam (Pricking pain):** In Group A reduction of 70% ( $p<0.01$ ) was noted and in group B reduction of 70% ( $p <0.01$ ) was noted. This reduction was insignificant ( $p>0.05$ ) while comparing between groups.

**Table 5:** Effect on Symptoms

<i>Chimichimayana</i>	Mean		W-rank	p value
Group A	1.3 (BT)	0.5(AT)	T+=28; T-=0	$p<0.05$
Group B	0.8 (BT)	0.1 (AT)	T+=15; T-=0	$p<0.05$
Comparison	0.8 (Group A)	0.7 (Group B)	U static =44.5	$p>0.05$
<i>Supti</i>				
Group A	1.7 (BT)	1 (AT)	T+=21; T-=0	$p<0.01$
Group B	2 (BT)	0.9 (AT)	T+=55; T-=0	$p<0.01$
Comparison	0.7 (Group A)	1.1(Group B)	U static=32	$p>0.05$
<i>Karapada daha</i>				
Group A	2.1 (BT)	0.7 (AT)	T+=36; T-=0	$p<0.001$
Group B	2(BT)	0.2 (AT)	T+=0; T-=0	$p<0.001$
Comparison	1.4 (Group A)	1.8 (Group B)	U static =37	$p>0.05$
<i>Todam</i>				
Group A	1.9 (BT)	0.7 (AT)	T+=36; T-=0	$p<0.01$
Group B	1.6 (BT)	0.4 (AT)	T+=36; T-=0	$p<0.01$
Comparison	1.2 (Group A)	1.2(Group B)	U static=50	$p>0.05$

**6.Effect of therapy on blood sugar level:**

**Effect on FBS:** In Group A, reduction of 5.4% (p>0.05) and in Group B, reduction of 11.2% (p<0.01) were noted. This reduction was statistically insignificant(p>0.05) while comparing between groups.

**Effect on PPBS:** In Group A, there was an increase of 4.6% & the p value was statistically insignificant (p>0.05). In Group B, there was a reduction of 11.1% (p<0.05). On comparison between groups, showed statistically insignificant (p>0.05).

**Table 6:** Effect on blood sugar level

FBS	Mean		t-value	p value
Group A	151 (BT)	135.4 (AT)	1.04	P>0.05
Group B	144.2 (BT)	127.9 (AT)	4.53	p<0.01
Comparison	15.6(Group A)	16.3 (Group B)	0.04	p>0.05
PPBS				
Group A	250.6 (BT)	262.2(AT)	0.7	p>0.05
Group B	254.1(BT)	237.4 (AT)	1.8	p<0.05
Comparison	11.6(Group A)	27.7(Group B)	2.4	P<0.05

**RESULT & DISCUSSION**

Avarana (either by *kapha* or by *pitha*) causing *avarodha* to the normal *gati* of *vaata* and leading to *vaata* vitiation in DPN. Impaired touch sensation, pain, vibration, *supti*, *chimichimayana* etc. are the manifestations of vitiated *vaata*. *Takradhara drava* by virtue of its procedural effect- *pitha vatahara* and medicinal effect-*Kapha vata hara*, helps to relieve this *margavarodha*. In *sarvanga takradhara*, the potency of the drug administered through *parisheka* will traverses from the skin into the body getting processed by the effect of *bhrajaka pitha*. This *pitha* causes *vilayana* for *kapha* & removes *avaranam*. So, when *vata dosha* is coming down, feeling of *chimichimayana* etc. will reduce. Also, *shirotakradhara* causes normal functioning of central nervous system. So abnormal sensations produced by the CNS will reduced by *shirotakradhara*.

*Prameha* with the increase in chronicity, the *paithika* bhavas takes over the pathology and produce burning sensations increased thirst, sweating etc. *Ushnata* in body leading to *kapha vilayana* and *soumya* bhavas expelled through urine, sweat etc. This leads to *soumya bhava sosana* in the body and increase of *vata pitha dosha*. *Seeta sparsa* and *Vata pitha samana* effect of *dhara* procedure reduces these symptoms in DPN.

Diminished reflexes and muscle power in DPN occurred in the later stage of disease, ie *kevala vatika*. All *kevala vatika pramehas* are *asadhya*.

**Probable mode of action:** Various researches proved that *Takradhara* can reduce blood glucose level<sup>19</sup>&cortisol hormone level<sup>20</sup>.*Takradhara* is having *sama sitoshna* and *sthambhana* properties. Aggravated *Usna* and *sara guna* of *pitha dosha* is coming to normalcy by *sita* and *sthambhana* property. *Pitha* is a major factor helping in endocrine secretion by its *ushna* and *sara* property. *Vata dosha* is helping to give movements for proper functioning of all endocrine secretions by its *chalaguna*. So, when cortisol level increases, *vata pitha dosha* vitiation occurs. *Takradhara* can relieve this *Vata pitha dosha kopa* by its *sita sparsa* effect, *sthambhana* effect, procedural effect of *dhara* etc. Also, *takradhara* gives relaxation to neural impulses which cause shortening of CRH and it is controlling the ACTH production along with vasopressin and helps to reduce plasma cortisol level. In total, the cumulative effect of all these cause reductions of symptoms of DPN after *Takradhara*. But compared to the *Sarvanga takradhara* group, there was much reduction of blood glucose levels in the *shiro Takradhara* group. It may be due to direct action of *takradhara* on brain.

## CONCLUSION

Both *Sarvanga takradhara* and *Shiro takradhara* are equally effective in reducing signs and symptoms of DPN. *Shirotakradhara* is effective in reducing blood sugar level (FBS and PPBS). *Sarvanga takradhara* does not produce significant effect in reducing blood sugar level ( FBS and PPBS)

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