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A Comparative Pharmaceutico-Clinical Study to Evaluate the Efficacy of *Pinda Taila* and *Khajita Pinda Taila* in the Symptomatic Management of *Daha* and *Shoola* of *Vatarakta* w.s.r to Diabetic Neuropathy

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ABSTRACT

Background: *Vatarakta* is a clinical manifestation explained in the Ayurvedic classics having the involvement of both *Vata Dosha* and *Rakta Dhatu*. It is a disease predominantly affecting the extremities mainly the *Pada* and *Hasta*. Due to the similarity in the pathology of *Vatarakta* and Diabetic neuropathy, many symptoms like *Daha* and *Shoola* which are manifested in *Vatarakta* are also observed to be manifested in Diabetic Neuropathy. *Pinda Taila* is one such formulation mentioned in our classics to be used for the relief of *Daha* and *Shoola* developed in *Vatarakta* after doing *Manthana Samskara* to it. **Aims and objectives:** To evaluate the efficacy of *Pinda Taila* and *Khajita Pinda Taila* in the symptomatic management of *Daha* and *Shoola* of Diabetic Neuropathy. **Materials and methods:** Forty patients diagnosed with Diabetic Neuropathy suffering from *Daha* and *Shoola* were selected for the study. **Results and Conclusion:** *Pinda Taila* showed statistically significant results in the management of *Shoola* whereas *Khajita Pinda Taila* was observed to be statistically efficacious in the management of the symptom *Daha*.

KEYWORDS

Khajita Pinda Taila, *Vatarakta*, Diabetic Neuropathy, *Daha*, *Shoola*



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INTRODUCTION

Vatarakta is a unique clinical manifestation explained in the Ayurvedic classics having the involvement of both *Vata Dosha* and *Rakta Dhatu*¹. It is a *Vyadhi* predominantly affecting the extremities mainly the *Pada* and *Hasta*. The obstruction to the flow of *Vata Dosha* as well as *Rakta Dhatu* is the main pathology involved. This pathology in *Vatarakta* is possible by the occurrence of *Raktamarga Avarana* due to variant modes of etiological factors where *Santarpana Ahara* and *Vihara* play a crucial role. A person when indulges in these etiological factors, proves to result in excessive accumulation of abnormal *Kapha Dosha* and *Medo Dhatu* in the *Raktavaha Srotas* which is one of the leading pathology involved in the causation of diseases occurring in any part of the body. The same etiopathogenesis along with *Vatarakta* can also be observed in *Prameha*, *Sihoulya* and *Shonita Dushti*. Due to this similarity in the pathology, many symptoms like *Daha* and *Shoola* which are manifested in *Vatarakta* are also observed to be manifested in Diabetic Neuropathy. Diabetic Neuropathy is a nerve damaging disorder associated with diabetes mellitus. This condition is said to be the result of diabetic micro-vascular injury involving small blood vessels. Diabetic Neuropathy affects all

peripheral nerves including sensory and motor neurons. The clinical manifestation of Diabetic Neuropathy can show varied symptoms like burning sensation in the foot, paraesthesia, dysesthesia, numbness etc².

*Pinda Taila*³ is one such Yoga mentioned in our classics for the relief of *Daha* and *Shoola* developed in *Vatarakta* after subjecting it to *Khajita Samskara/Manthana Samskara*. (i.e. churning). As many Ayurvedic physicians are successfully practicing the application of *Khajita Pinda Taila*³ in the symptomatic management of Diabetic Neuropathy, a comparative study was taken up to evaluate the efficacy of *Pinda Taila* and *Khajita Pinda Taila* in the symptomatic management of *Daha* and *Shoola* of *Vatarakta* w.s.r to Diabetic Neuropathy.

AIMS AND OBJECTIVES

To evaluate and compare the efficacy of *Pinda Taila* and *Khajita Pinda Taila* in symptomatic management of *Daha* and *Shoola* of Diabetic Neuropathy through clinical study.

Ethical Committee Clearance Number-SDMCAU/ACA-49/ECA26/15-16.

MATERIALS AND METHODS

Source of data:



Forty patients attending the OPD and IPD of SDM Ayurveda Hospital, Udipi, Karnataka diagnosed with Diabetic Neuropathy fulfilling the inclusion and exclusion criteria were selected for the study.

Methods of collection of data:

A complete profile of the patient was prepared (Table 1) including all the details of history taking including the symptomatology, physical signs and symptoms, patients' *Prakriti* along with elaborate assessment of pain and burning sensation using standard questionnaires and examination techniques.

Table 1 Observations according to different demographic data of patients

Sl.No.	Variables	Observations			
		Group 1		Group 2	
		Maximum incidence	Percentage	Maximum incidence	Percentage
01.	Age	60-70	75%	60-70	60%
02.	Gender	Male	85%	Female	60%
03.	Religion	Hindu	95%	Hindu	95%
04.	Educations	Graduate	80%	Graduate	45%
05.	Marital status	Married	95%	Married	100%
06.	Socio-economic status	Middle class	85%	Middle class	85%
07.	Occupation	Sedentary	60%	Strenuous	70%
08.	Place	Urban	80%	Urban	60%
09.	Duration of diabetes	0-10 years	65%	0-10 years	75%
10.	Duration of Diabetic Neuropathy	5-6 months	35%	3-4 months	25%
11.	Nature of work	Standing for long hours	40%	Standing for long hours	25%
12.	Diet	Vegetarian and mixed	50% each	Vegetarian	75%
13.	Appetite	Good	90%	Good	85%
14.	Habits	<i>Vishamashana</i>	45%	<i>Vishamashana</i>	30%
15.	<i>Rasapradhanata in Ahara</i>	<i>Combination of katu-amla-lavana</i>	80%	<i>Combination of katu-amla-lavana</i>	50%
16.	<i>Prakriti</i>	<i>Vatapitta</i>	65%	<i>Vatapitta</i>	55%
17.	<i>Sara</i>	<i>Madhyama</i>	80%	<i>Madhyama</i>	60%
18.	<i>Pramana</i>	<i>Madhyama</i>	85%	<i>Madhyama</i>	80%
19.	<i>Samhanana</i>	<i>Madhyama</i>	85%	<i>Madhyama</i>	80%
20.	<i>Satwa</i>	<i>Madhyama</i>	85%	<i>Madhyama</i>	75%
21.	<i>Satmya</i>	<i>Madhyama</i>	85%	<i>Madhyama</i>	80%
22.	<i>Ahara Shakti</i>	<i>Madhyama</i>	85%	<i>Madhyama</i>	75%
23.	<i>Vyayama Shakti</i>	<i>Madhyama</i>	85%	<i>Madhyama</i>	80%
24.	Site of the disease	<i>Pada</i>	55%	<i>Pada</i>	40%
25.	Symptoms	Pain and burning	35%	Pain and burning	30%

Inclusion Criteria

1. Patients between the age group of 30 -70 yrs.
2. Patients diagnosed with Diabetic Neuro-

pathy and suffering from *Daha* and *Shoola*.

Exclusion Criteria

1. Any clinical manifestations with ulceration/



gangrene/ edema/ any skin lesion in the affected area.

Design of the Study

- **Group ‘A’** Diabetic Neuropathy patients suffering from *Daha* and *Shoola* were applied with *Pinda Taila* only.
- **Group ‘B’** Diabetic Neuropathy patients suffering from *Daha* and were applied with *Khajita Pinda Taila* only.

Intervention:

External application of *Pinda Taila* and *Khajita Pinda Taila* was done for 7 days. Each day application was done to the affected area for two times i.e morning and evening for maximum of fifteen minutes⁴.

Follow Up Period: 7 days

Duration Of The Study: 14 days

Assessment Criteria

The patients’ response was assessed on the basis of subjective and objective parameters and analyzed statistically by Wilcoxon Signed Rank test and Mann Whitney test.

Subjective Parameters

Assessment Scale for Pain:

- a) 0 No pain
- b) 1-2 Can be ignored- mild
- c) 3-4 Interferes with tasks- moderate
- d) 5-6 Interferes with concentration- moderate
- e) 7-8 Interferes with basic needs- severe
- f) 9-10 Bed rest required- worst

Assessment Scale for Burning Sensation:

- a) 0 No burning sensation
- b) 1-2 Can be ignored- mild
- c) 3-4 Interferes with tasks-moderate
- d) 5-6 Interferes with concentration- moderate
- e) 7-8 Interferes with basic needs –severe
- f) 9-10 Bed rest required-worst

Objective Parameters

- Tuning fork test
- Peripheral pulse
- Deep tendon reflexes

Investigations:

1. Fasting blood sugar.
2. Post-prandial blood sugar.

DISCUSSION ON RESULTS

DISCUSSION ON SUBJECTIVE PARAMETERS

Discussion of the effect on Pain:

In group 1 (*Pinda Taila*), statistically highly significant results were found in the reduction of the symptom pain when compared to group 2 (*Khajita Pinda Taila*) with p value 0.000, Z value -3.500 in group 1 (Table 2). Moreover, statistically significant results were also found in the group 2 with p value 0.004 and Z value -2.818 (Table 4). From the above statement we can infer that *Pinda Taila* had better efficacy in the management of the symptom pain as compared to *Khajita Pinda Taila*.



However, *Khajita Pinda Taila* also has mild action in relieving the pain.

Discussion on the effect on Burning sensation:

Statistically highly significant results were observed in the reduction of the symptom burning sensation in both the groups with p value 0.001 and Z value -3.317 in group 1 (Table 2) and p value 0.001 and Z value -3.432 in group 2 (Table 4). However, after

the follow up period, group 1 showed only statistically significant results (Table 2) whereas group 2 showed highly significant results even after follow up period (Table 4). It can be inferred from the above statements that, *Khajita Pinda Taila* showed better and prolonged action on the symptom Burning sensation when compared to *Pinda Taila*.

Table 2 Statistical analysis of subjective parameters (Wilcoxon signed rank test) of *Pinda Taila*

SUBJECTIVE PARAMETERS						
Variables	Z value		p value		Inference	
	BT-AT	BT-FU	BT-AT	BT-FU	BT-AT	BT-FU
Pain	-3.500	-3.500	.000	.000	HS	HS
Burning sensation	-3.317	-3.051	.001	.002	HS	S
Pins & needles	-1.000	-1.000	.317	.317	NS	NS
Tingling sensation	.000	.000	1.000	1.000	NS	NS

Table 3 Statistical analysis of objective parameters (Wilcoxon signed rank test) of *Pinda Taila*

OBJECTIVE PARAMETERS												
Parameters	DATA	Negative ranks			Positive ranks			Ties	Total	Z value	p value	Inference
		N	MR	SR	N	MR	SR					
Tuning fork test	BT-AT	0	.00	.00	2	1.50	3.0	18	20	-1.414	.157	NS
	BT-FU	0	.00	.00	2	1.50	3.0	18	20	-1.414	.157	NS
Peripheral pulse	BT-AT	0	.00	.00	1	1.00	1.0	19	20	-1.000	.317	NS
	BT-FU	0	.00	.00	1	1.00	1.0	19	20	-1.000	.317	NS
Deep tendon reflexes	BT-AT	0	.00	.00	0	.00	.0	20	20	.000	1.000	NS
	BT-FU	0	.00	.00	0	.00	.0	20	20	.000	1.000	NS

Discussion on the effect on Pins and needles, Tingling sensation and Numbness:

Statistically Non- significant results were found in both the groups for the symptoms

Pins and Needles, Tingling sensation and Numbness. Hence it can be stated that, Hence it can be concluded that, both the *Taila* do not have any action on these symptoms.



Table 4 Statistical analysis of subjective parameters (Wilcoxon signed rank test) of *Khajita Pinda Taila*

Variables	Z value		p value		Inference	
	BT-AT	BT-FU	BT-AT	BT-FU	BT-AT	BT-FU
Pain	-3.500	-3.500	.000	.000	HS	HS
Burning sensation	-3.317	-3.051	.001	.002	HS	S
Pins & needles	-1.000	-1.000	.317	.317	NS	NS
Tingling sensation	.000	.000	1.000	1.000	NS	NS
Numbness	.000	.000	1.000	1.000	NS	NS

Table 5 Statistical analysis of objective parameters (Wilcoxon signed rank test) of *Khajita Pinda Taila*

OBJECTIVE PARAMETERS

Parameters	DATA	Negative ranks			Positive ranks			Ties	Total	Z value	p value	Inference
		N	MR	SR	N	MR	SR					
Tuning fork test	BT-AT	0	.00	.00	2	1.50	3.00	18	20	-1.414	.157	NS
	BT-FU	0	.00	.00	2	1.50	3.00	18	20	-1.414	.157	NS
Peripheral pulse	BT-AT	0	.00	.00	1	1.00	1.00	19	20	-1.000	.317	NS
	BT-FU	0	.00	.00	1	1.00	1.00	19	20	-1.000	.317	NS
Deep tendon reflexes	BT-AT	0	.00	.00	0	.00	.00	20	20	.000	1.000	NS
	BT-FU	0	.00	.00	0	.00	.00	20	20	.000	1.000	NS

DISCUSSION ON OBJECTIVE PARAMETERS

Discussion on the effect on tuning fork test, peripheral pulse and deep tendon reflexes:

When both the groups were statistically analyzed for the effect on the above symptoms, statistically non-significant results were obtained in both the groups (Table 3, 5). This may be due to non-progressed state of the disease condition in patients.

PROBABLE MODE OF ACTION OF

PINDA TAILA AND KHAJITA PINDA TAILA

The therapeutic properties of the drugs like, *Sariva*, *Manjishta*, *Sarjarasa* and *Madhuchishta* are more of *Raktaprasadaka*, *Varnya*, *Twachya* which are essentially required properties in the condition like *Shonita Dushti*. As *Rakta Dhatu* has properties similar to *Pitta Dosha* like *Ushna*, *Tikshna* etc, the symptom *Daha* manifested in *Vatashonita* is also caused mainly due to the vitiation of *Rakta Dhatu*. With *Sariva* and *Sarjarasa* having *Sheeta*



Virya as their inherent properties, they might have helped in better absorption as well as reducing the symptom *Daha*. Along with the inherent properties of the ingredients, the *Manthana Samskara* adopted in *Khajita Pinda Taila* might have enhanced the *Sheeta Guna* of the formulation and helped in reducing the symptom *Daha* predominantly.

Tila Taila is best known for its *Vatahara* and *Shoolahara* properties. Along with *Taila*, the ingredients like *Manjishta* and *Madhuchishta* are said to have *Ushna Virya* and *Vatarakta Nashana* property. These properties of the ingredients of *Pinda Taila* might have worked in the reduction of the symptom *Shoola* in *Vatarakta*. On the whole, the properties of the ingredients of *Pinda Taila* and *Khajita Pinda Taila* along with the *Manthana Samskara* prove to be beneficial in the management of *Shoola* and *Daha* of Diabetic Neuropathy.

CONCLUSION

Vatarakta in contemporary view can be included under the umbrella of collagen vascular disorders which includes all types of connective tissue disorders. This comparison can be understood based on the similarities in the symptomatology of the diseases *Vatarakta* as well as collagen vascular disorders. The two types of

pathology as already mentioned above, are responsible for the manifestation of *Vatarakta*. Out of the two pathologies, the one caused due to excessive accumulation of *Kapha Dosha* and *Medo Dhatu* in the *Rakta Marga* is similar to the pathology of Diabetic Neuropathy. The therapeutic properties of the drugs like, *Sariva* (*Hemidismus Indicus*), *Manjishta* (*Rubia cardifolia*), *Sarjarasa* (*Shorea robusta* resin) and *Madhuchishta* (bee wax) are more of *Raktaprasadaka* (blood nourishing), *Varnya* (gives complexion), *Twachya* (good for skin) which are essentially required properties in the condition like *Shonita Dushti* (disorders due to blood). On this basis, the selection of formulation based on the diagnosis like *Shonita Dushti* is also more appropriate. Hence in this study, *Khajita Pinda Taila* showed statistically significant improvement in the management of the symptom *Shoola* but *Pinda Taila* showed statistically highly significant results in the management of the symptom *Shoola* when compared to *Khajita Pinda Taila*. *Pinda Taila* showed statistically significant improvement in the management of the symptom *Daha* but *Khajita Pinda Taila* showed statistically highly significant results with respect to the symptom *Daha* when compared to *Pinda Taila*.



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