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A Clinical Study to Evaluate the Efficacy of *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: The transformation of properties from a raw drug in to a formulation is made possible by the use of various processing techniques named Samskaras. Manthana Samskara is said to imbibe Sheeta Guna to a formulation as Sheeta Jala is used in the process. Vatarakta 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. The same etiopathogenesis along with Vatarakta can also be observed in Prameha, Sthoulya 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. Pinda Taila 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. **Aims and objectives:** To evaluate the efficacy of Khajita Pinda Taila in the symptomatic management of Daha and Shoola of Diabetic Neuropathy. **Materials and methods:** 20 patients diagnosed with Diabetic Neuropathy suffering from Daha and Shoola were selected for the study. **Results and Conclusion:** Khajita Pinda Taila was observed to be statistically efficacious in the management of the symptom Daha than Shoola.

KEYWORDS

Khajita Pinda Taila; Daha; Shoola



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INTRODUCTION

Bhaishajya Kalpana is considered as Ayurvedic Pharmaceutics which plays an eminent part in the processing of the raw drugs into formulations for the treatment of numerous ailments. These processes or transformation of properties from a raw drug in to a formulation is made possible by the use of various processing techniques. The same techniques adopted are termed as Samskaras¹ in Ayurveda. These Samskaras are selected depending on either the nature of the raw drug to be processed or the disease to be treated. Hence, Samskaras play a pivotal role in imbining certain qualities to the drug bestowing it with better therapeutic properties. This specificity in selecting ideal Samskara for Dravyas, played the key factor behind formulating an effective dosage form in classical Ayurvedic texts. One such Samskara explained in our classics is Manthana Samskara(Churning)¹. Manthana Samskara is adopted in formulations which are predominantly in liquid consistency i.e either water as base or oil. Manthana Samskara is believed to help in the proper mixing of two substances. It is considered to give a homogenous mixture thereby improving the product's stability to a greater extent. Also, Manthana Samskara is said to imbibe Sheeta Guna to a formulation

as Sheeta Jala is used in the process as seen in Mantha Kalpana by continuous rotation of the instrument placed inside the liquid media. So to know the impact of Manthana Samskara, a combination of Toya Sannikarsha and Manthana Karma, in providing Sheeta Guna to a formulation, this study was taken up.

Vatarakta² 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. The same etiopathogenesis along with Vatarakta can also be observed in Prameha, Sthoulya 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 Neuropathy³. Pinda Taila⁴ 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 Taila⁵ in the symptomatic management of Diabetic Neuropathy, this study was taken up to revalidate the experience of the physicians in the management of Diabetic Neuropathy.



OBJECTIVES OF THE STUDY

1. To evaluate the efficacy of Khajita Pinda Taila in the symptomatic management of Daha and Shoola of Diabetic Neuropathy.

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

Pharmaceutical preparation of Khajita Pinda Taila

Initially, Pinda Taila⁴ was prepared using Murchita Tila Taila⁶ and Kalka Dravyas as Manjishta, Sariva, Madhuchishta and Sarjarasa. To the obtained final product of Pinda Taila equal quantity of cold water was added and churned using an electric motor churner until a thick or buttery consistency of the oil was obtained. This prepared emulsion was then stored in wide mouthed air tight containers and labelled.

MATERIALS AND METHODS

Source of data:

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

Methods of collection of data:

20 patients attending the OPD and IPD of SDM Ayurveda Hospital, Udupi, Karnataka diagnosed with Diabetic Neuropathy suffering from Daha and

Shoola and fulfilling the inclusion and exclusion criteria were selected for the study. A complete profile of the patient was prepared 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.

Inclusion Criteria

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

It was an open clinical study with minimum 20 patients diagnosed with Diabetic Neuropathy suffering from Daha and Shoola and fulfilling the inclusion and exclusion criteria were randomly selected.

Intervention:

External application of 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 minutes⁷.

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.

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

OBSERVATIONS AND RESULTS

Demographic Data

Table 1 Distribution of patients according to different demographic variables.

| Sl.No. | Variables | Observations in Maximum incidence | Percentage |
|--------|---------------------------------|-----------------------------------|------------|
| 01. | Age | 60-70 | 60% |
| 02. | Gender | Female | 60% |
| 03. | Religion | Hindu | 95% |
| 04. | Educations | Graduate | 45% |
| 05. | Marital status | Married | 100% |
| 06. | Socio-economic status | Middle class | 85% |
| 07. | Occupation | Strenuous | 70% |
| 08. | Place | Urban | 60% |
| 09. | Duration of diabetes | 0-10 years | 75% |
| 10. | Duration of Diabetic Neuropathy | 3-4 months | 25% |
| 11. | Nature of work | Standing for long hours | 25% |
| 12. | Diet | Vegetarian | 75% |
| 13. | Appetite | Good | 85% |
| 14. | Habits | Vishamashana | 30% |
| 15. | Rasapradhanata in Ahara | Combination of katu-amla-lavana | 50% |
| 16. | Prakriti | Vatapitta | 55% |
| 17. | Sara | Madhyama | 60% |
| 18. | Pramana | Madhyama | 80% |
| 19. | Samhanana | Madhyama | 80% |
| 20. | Satwa | Madhyama | 75% |
| 21. | Satmya | Madhyama | 80% |



| | | | |
|-----|---------------------|------------------|-----|
| 22. | Ahara Shakti | Madhyama | 75% |
| 23. | Vyayama Shakti | Madhyama | 80% |
| 24. | Site of the disease | Pada | 40% |
| 25. | Symptoms | Pain and burning | 30% |

RESULTS AND DISCUSSION

Discussion on Subjective Parameters

Discussion of the effect on Pain:

- Results were compared before and after treatment for the variable Pain, significant

results were obtained with 'Z' value -2.850 and 'p' value 0.004 (Table 2). From the above results it can be inferred that Khajita Pinda Taila does not have significant effect in the reduction of pain.

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

| 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 |

Discussion of the effect on Burning sensation

- Results were compared before and after treatment for the variable Burning Sensation, highly significant results were obtained with 'Z' value -3.330 and 'p' value 0.001 (Table 2). From the above statement we can infer that Khajita Pinda Taila had better efficacy in the management of Burning sensation.

Discussion of the effect on pins and needles

- Results were compared before and after treatment for the variable pins and needles, Significant results were obtained with 'Z' value -2.585 and 'p' value 0.010 (Table 2).

Hence it can be stated that, Khajita Pinda Taila showed significant action in relieving pin prick sensation.

Discussion on the effect on Tingling sensation

- Results were compared before and after treatment for the variable Tingling sensation, Non Significant results were obtained with 'Z' value 0.000 and 'p' value 1.000 (Table 2). Hence it can be concluded that, Khajita Pinda Taila does not have any action on the symptom tingling sensation.

Discussion on the effect on Numbness

- Results were compared before and after treatment for the variable Numbness, Non-Significant results were obtained with 'Z'



value -1.000 and ‘p’ value 0.317 (Table 2). Hence it can be concluded that, Khajita Pinda Taila does not have any action on the symptom numbness.

DISCUSSION ON OBJECTIVE PARAMETERS

Discussion on the effect on tuning fork test

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

| Param eters | DATA | Negative ranks | | | Positive ranks | | | Ties | Total | Z value | p value | Inferenc e |
|----------------------|-------|----------------|-----|-----|----------------|------|------|------|-------|---------|---------|------------|
| | | 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 |
| Periph eral 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 effect on the peripheral pulse

Results were compared before and after treatment for the variable Peripheral pulse, Non-Significant results were obtained with ‘Z’ value 0.000 and ‘p’ value 1.000(Table 3). These results show that Khajita Pinda Taila does not have any action on the improvement of peripheral pulse.

Discussion on effect on the deep tendon reflexes

Results were compared before and after treatment for the variable Deep tendon

Results were compared before and after treatment for the variable Tuning Fork Test, Significant results were obtained with ‘Z’ value -2.449 and ‘p’ value 0.014(Table 3). This may be due to non-progressed state of the disease condition in patients.

reflexes, Non-Significant results were obtained with ‘Z’ value 0.000 and ‘p’ value 1.000(Table 3). Before treatment when the deep tendon reflexes were examined, there were no abnormalities detected in the reflexes. Hence there was no change observed in the parameter deep tendon reflexes after treatment as well.

PROBABLE MODE OF ACTION OF 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.

CONCLUSION

Vatarakta comes under the umbrella of Collagen Vascular Diseases in the contemporary science. This correlation can be justified by the similarities in the pathology of both the diseases i.e. the pathology of accumulation of Kapha Dosha and Meda Dhatu in the Rakta Marga can be appreciated in both the ailments. Diabetic Neuropathy involving the same pathology can also be considered as Vatarakta. 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. Along with the inherent properties of the ingredients, the Manthana Samskara adopted in Khajita Pinda Taila enhanced the Sheeta Guna of the formulation and helped in reducing the symptom Daha predominantly.



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