Research Article

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SHAMANA SNEHAPAANA WITH KOTTAMCHUKKADI TAILA IN CARPAL TUNNEL SYNDROME WITH SPECIAL REFERENCE TO SNEHAPAANA: A RANDOMIZED DOUBLE BLIND CLINICAL TRIAL

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ABSTRACT

Kottamchukkadi Taila is recommended for shamana snehapaana in Carpal Tunnel Syndrome by physicians across Kerala. The results are encouraging with no complications being reported. Also a unanimous opinion regarding the exact snehapaana to be administered for snehapaana is not available in classics of Ayurveda. In the present trial, 66 participants satisfying the eligibility criteria were selected from OPD of VPSV Ayurveda College Hospital Kottakkal and allocated into three groups namely Group A, B and C and administered shamana snehapaana with Kottamchukkadi taila in mrdu, madhyama and khara paaka respectively in a dose of 25- 200 ml. The duration of treatment was upto vyaadhi upashama or maximum upto 15 days. Safety was assessed on Event Evaluation Scale daily and objective assessment by blood parameters namely Blood R/E, FBS, LFT, RFT, Lipid profile before and after treatment. Assessment of efficacy was done before treatment, after treatment and after follow up of 30 days on Symptom Severity Scale and Functional Status Scale. Statistical analysis was done by paired t test and one way ANOVA. No adverse effects were observed and shamana snehapaana in all three paaka was effective in reducing Symptom Severity and Functional Status score in Carpal Tunnel Syndrome.

Key words: Shamana Snehapaana, Kottamchukkadi Taila, Carpal Tunnel Syndrome, Snehapaaka

INTRODUCTION

Shamana Snehapaana is a common procedure for alleviating many diseases which can be practiced at outpatient department and can be given at night without interfering with the daily activities of patient. Even though many benefits are conferred to this procedure, Shamana Snehapaana is an unexplored area in Ayurveda.

Kottamchukkadi Taila, a commonly used Ayurveda formulation is widely practiced for external application in vaata vitiation disorders. Many Physicians across Kerala also recommend its internal use and no complications have been reported so far. Considering safety aspects on internal use, almost all ingredients are katu, tikta rasa, katu vipaaka, ushna veerya, kapha vaatahara and non toxic.

Kottamchukkadi Taila available in the market is prepared in khara paaka only. A unanimous opinion regarding the exact snehapaaka which should be used for snehapaana is not available in classics of Ayurveda.

The claims of safety and efficacy of Shamana Snehapaana with Kottamchukkadi Taila are not supported either by concrete

research work or by powerful statistical tools. Hence, to support these claims, this clinical trial was conducted with the objective:

- To study the safety and efficacy of Shamana Snehapaana with Kottamchukkadi Taila prepared in mrdu, madhyama and khara paaka in Carpal Tunnel Syndrome.

MATERIALS AND METHODS

A detailed Case record form, Consent form, Information leaflet, Samyak snigdha lakshana assessment chart, Event evaluation scale, Symptom Severity Scale and Functional Status scale.

Present study was carried out in accordance with ethical principles by following International Conference of Harmonization- Good Clinical Practices Guidelines [ICH-GCP].

Informed consent: A Consent form in regional language (Malayalam) was prepared and prior consent of all participants was obtained.

Ethical committee clearance: The study synopsis was placed before Institutional Ethics Committee of V.P.S.V Ayurveda College, Kottakkal (IEC/CL/17/13 dated 22/04/2013) and ethical clearance was obtained.

Table 1: Diagnostic criteria

Symptoms (any one is essential)	Signs (any one is essential)
Pain in the hand	Tinel's sign
Numbness in the hand	Wrist Flexion Test
Tingling sensation in the hand	(Phalen's maneuver)
Weakness of hand	

Table 2: Inclusion Criteria

Inclusion criteria
Age- 20 – 60 years
Sex- no discrimination
Agni- Samaagni
Koshtha- Madhyama or Krura
Snehapaana arha
Participants giving informed consent

Table 3: Exclusion Criteria

Exclusion criteria
Clinically diagnosed Rheumatoid Arthritis
Recent H/O trauma and/ or fracture of wrist joint
Uncontrolled Hypertension
Pregnant and lactating women
Acid peptic disease
Participants taking modern medications for Carpal Tunnel Syndrome
Thenar muscles wasting

The study design was Randomized Double Blind Clinical Trial. Sixty six participants who attended the OPD of VPSV Ayurveda College, Kottakkal during the study period satisfying the eligibility criteria were selected and randomized as per random number table.

A detailed examination was done on the day zero and details were recorded in the case record form. After treatment, examination was done on day 15 and a follow up was done after 30 days of completion of snehapaana.

Table 4: Group allocation and details of intervention

Particulars	Group A	Group B	Group C
No. of participants	22	22	22
Trial Drug	Kottamchukkadi Taila (mrdu paaka)	Kottamchukkadi Taila (madhyama paaka)	Kottamchukkadi Taila (khara paaka)
Dose	25- 200 ml	25- 200 ml	25-200 ml
Duration	Upto Vyaadhi upashama (or max. 15 days)	Upto Vyaadhi upashama (or max. 15 days)	Upto Vyaadhi upashama (or max. 15 days)
Anupaana	Luke warm water	Luke warm water	Luke warm water
Time	9-10 pm (on good appetite)	9-10 pm (on good appetite)	9-10 pm (on good appetite)
Diet before Snehapaana	Kanji at 6 pm	Kanji at 6 pm	Kanji at 6 pm

Availability of trial drug

The trial drug- Kottamchukkadi taila was prepared in three different paaka and purchased from a GMP certified company- Oushadhi, The Pharmaceutical Corporation (I.M) Kerala Ltd., Thrissur.

Batch number- 5796/C/2013-14

Assessment criteria for safety of sneha paana**Subjective Parameters**

Event Evaluation Scale (EES)

Assessment was done daily.

Objective Parameters

1. Liver Function Tests
2. Renal Function Tests
3. Lipid profile
4. Blood routine

5. FBS

Assessment on these was done before and after intervention.

Assessment criteria for efficacy of snehapaana

1. A self administered questionnaire for the assessment of severity of symptoms and functional status in patients of Carpal Tunnel Syndrome
 2. A functional Status Scale
- Assessment on these was done before intervention, after intervention and after follow up.

Data Analysis

The data collected was subjected to statistical analysis with the help of Microsoft Excel-7 software by using Paired t-test, one way ANOVA and post hoc test (Sidak multiple comparison test). 5% was fixed as significance level.

Table 5: Laboratory findings for assessment of safety of snehapaana

Parameters	Group A		Group B		Group C	
	Mean	Difference + Standard Deviation	t value	Mean	Difference + Standard Deviation	t value
Total cholesterol	3	+ 19.78	0.71	4	+ 13.01	1.44
Triglycerides	4	+ 18.19	1.03	2.4	+ 29.72	-0.41
HDL	0.3	+ 3.13	0.40	0.3	+ 3.55	0.48
LDL	3.7	+ 19.14	0.90	2.6	+ 14.76	0.83
VLDL	1.8	+ 4.80	1.77	0.2	+ 7.33	0.11
Hb	0.07	+ 0.61	-0.52	0.1	+ 0.48	-0.22
TLC	177.2	+ 1187.6	0.70	54.6	+ 566.3	0.45
Neutrophils	0.7	+ 4.20	-0.81	1.1	+ 6.64	0.83
Lymphocytes	0.4	+ 4.82	0.44	1.6	+ 6.47	-1.15
Eosinophils	0.45	+ 1.63	1.31	0.18	+ 1.99	0.43
ESR	2.8	+ 5.73	1.82	4.3	+ 8.68	2.06
Fasting Blood Sugar	0.2	+ 13.44	0.06	1.9	+ 10.55	-0.84
SGOT	4.3	+ 13.53	1.51	2.1	+ 6.09	1.64
SGPT	5.6	+ 12.98	2.04	3.8	+ 9.60	1.82
ALP	2.9	+ 14.66	-0.92	1.5	+ 15.42	-0.45
Total Bilirubin	0.02	+ 0.07	1.33	0.01	+ 0.05	0.66
Indirect Bilirubin	0.02	+ 0.08	0.67	0	+ 0.04	-0.58
A/G ratio	0.07	+ 0.36	1.34	0.01	+ 0.21	-0.67
Serum creatinine	0.02	+ 0.11	0.60	0.02	+ 0.10	0.86
Serum Urea	0.3	+ 4.22	-0.28	0.2	+ 3.22	0.23
Serum Uric Acid	0.2	+ 0.86	1.21	0.2	+ 1.25	0.72

RESULTS

Safety of shamana snehapaana with Kottamchukkadi Taila

To analyze the before treatment and after treatment values of lab investigations, paired t test was used.

The changes observed in these lab parameters in all the groups were found to be statistically insignificant ($p > 0.05$). Hence, Shamana Snehapaana with Kottamchukkadi Taila prepared in mrdu, madhyama and khara paaka is safe.

Efficacy of Shamana Snehapaana with Kottamchukkadi Taila in Carpal tunnel syndrome Symptom Severity Scale

Graph 1: Effect of snehapaana on Symptom Severity Scale

Shamana snehapaana with Kottamchukkadi Taila was significant at $p < 0.01$ in reducing the Symptom Severity Score of Carpal tunnel syndrome in all the three groups as analyzed by paired t test and ANOVA.

Functional Status Scale

Graph 2: Effect of snehapaana on Functional Status Scale

On statistical analysis by paired t test and ANOVA, Shamana snehapaana with Kottamchukkadi Taila was significant at $p < 0.01$ in improving Functional status of Carpal tunnel syndrome in all the three groups.

Hence, Shamana snehapaana with Kottamchukkadi Taila in mr'du, madhyama and khara paaka is effective in Carpal tunnel syndrome.

To compare the effect of snehapaana between groups, ANOVA was used which was statistically insignificant ($p > 0.05$). Hence, all the three paaka were found equally effective.

DISCUSSION

Safety of shamana snehapaana

The changes observed after Shamana Snehapaana in Total Cholesterol, triglycerides, HDL, LDL, VLDL, Hb, TC, Neutrophils, eosinophils, Lymphocytes, FBS, Total Bilirubin, Indirect Bilirubin, Alkaline phosphatase, A/G ratio, Serum Urea, Serum Uric Acid, Serum Creatinine was statistically insignificant ($p > 0.05$).

Event Evaluation Scale

Nausea was the chief symptom observed among all the groups. The ingredients of Kottamchukkadi taila are having katu, tikta rasa, ushna, teekshna guna and katu vipaaka. Since they have lekhanitya property and an unpleasant taste, this might lead to mild irritation of gastric mucosa leading to development of nausea in the initial days of snehapaana. But towards the last days the nausea subsided gradually without any treatment.

Vomiting and pain in abdomen experienced by very few participants and subsided gradually and no treatment was needed for them. Apart from these, there were no complaints of shophahara, visamjnata, atisaara, jwara and aanaaha in any of the participants.

Efficacy of Shamana Snehapaana

Symptom Severity Scale

Symptom Severity Scale is a tool to assess the effect of treatment over the symptoms of Carpal Tunnel Syndrome i.e pain, numbness and weakness. Kapha avarana causing avarodha to the normal gati of vaata thereby leading to vaata vitiation is the basic pathogenesis in Carpal Tunnel Syndrome. Supti and shoola are the manifestations of vitiated vaata¹. Kottamchukkadi taila by virtue of its Kapha vata hara karma and ushna veerya helps to relieve this margavarodha caused by kapha and simultaneously pacify vaata by singdha, ushna guna which helps in the relief of numbness and pain and thereby reduction in symptom severity score. On comparison in between groups, no statistical significance was observed. Hence, the difference in paaka may have no role in the effect over symptom severity.

Functional Status Scale

The Functional Status Scale is a measure of functional disability for patients with Carpal Tunnel Syndrome. The symptoms of carpal tunnel syndrome i.e numbness and pain affect the functional status affecting the ability to do routine physical activities. Alpa balatvam or Bala haani i.e the inability to perform daily activities is a manifestation of vitiated vata.² In Carpal Tunnel Syndrome, margaavarodha caused by vitiated kapha leading to vaata vitiation at manibandha causes numbness and pain along with bala haani. Shamana snehapaana with Kottamchukkadi taila in all three paaka relieved kapha aavarana and facilitated pacification of vaata ultimately helped in the restoration of bala i.e the ability to perform routine activities is improved. Hence, in all three groups, significant change in functional status score was observed with no statistical significance on comparison between groups.

Drop outs

The number of drop outs in the present study was six. Two participants discontinued from each group. The drop outs were either due to inability to withstand nausea during the initial days of snehapaana or not attending phone calls regularly done for daily assessment.

Probable mode of action

The trial drug i.e Kottamchukkadi Taila is indicated for Vaataroga, Angastambha.³ On analyzing the composition of Kottamchukkadi Taila, it is kapha vaata shamana. Many of the dravyas produce lekhanitya, shothahara or shoolahara karma. Kushtha and Vacha are having lekhanitya property as per Charaka⁴. Shigru⁵, Lashuna⁶, Devadruma⁷ and Suvaha⁸ are having Shophahara action. Also Shunthi⁹, Shigru¹⁰, and Suvaha¹¹ are having shoolahaprashamana karma. Lashuna is also attributed the property of balya¹² and with its rasayana guna¹³, restores the cellular integrity. An analysis of rasa panchaka of Kottamchukkadi Taila reveals katu, tikta rasa, laghu, rooksha and teekshna guna. All the ingredients have ushna veerya and majority have katu vipaaka. In modern parlance, the anti inflammatory action of Kushtha¹⁴, Vacha¹⁵ and Shigru¹⁶ is reported. The analgesic action of Vacha¹⁷, Lashuna¹⁸, Cincha patra rasa¹⁹ has been reported. So Kottamchukkadi Taila which is having drugs performing lekhanitya, shophahara and deepana karma help in removing the kapha aavarana at manibandha and other shoolahaprashamana guna and brmhana drugs along with taila medium help in pacifying vaata.

The dosha dominance in Carpal tunnel syndrome is kapha vaata and taila has Samyogasamskaara²⁰ property. It is processed with shophahara, lekhanitya and shoolahara dravyas. On administering this taila as shamana snehapaana, the sneha properties like teekshna, sookshma, sara, vyavaayi guna facilitate the transport of shophahara, shoolahara and lekhanitya properties to madhyama roga marga which facilitate relieving the kapha association and help in pacifying vaata.

CONCLUSION

As per Ayurveda literature; Charaka, Vaagbhata, Haarita and Gada nigrha have advocated madhyama paaka for snehapaana whereas Sushruta endorsed mrdu paaka for snehapaana. In Sharangadhara samhita, madhyama paaka is told for all purposes i.e paana, abhyanga, basti and nasya. Hence there is no unanimous opinion regarding the concept of paaka even among aacharya. In present clinical trial, Shamana Snehapaana with Kottamchukkadi Taila proved to be safe and effective in all three groups as no significant difference was observed clinically.

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