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An explorative clinical study to evaluate the combined effect of *Nirgundi Taila Nasya* and *Chopachinyadi Choorna* in the management of Hypothyroidism

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ABSTRACT

Backgroud: Hypothyroidism is a hypometabolic clinical state, resulting from the reduction of thyroid hormone functions in the body. Prevalence of hypothyroidism in India is around 10.95% and females are more sufferers than males with ratio 6:1. Prevalence of subclinical hypothyroidism is 6 to 8% in women, 3% in men, and annual risk of developing clinical Hypothyroidism is about 4%. By observing the increasing incidence of hypothyroidism, this study was conducted as an attempt for finding better treatment protocol through the heritage of Ayurveda. **Objective of the study:** To evaluate the combined effect of *Nirgundi Taila Nasya* and *Chopachinyadi Choorna* with *Shigrupatra Kwatha* in the management of hypothyroidism. **Materials and Methods:** A single group open clinical study with pre-post test design was carried out in Government Ayurveda Medical College and Hospital, Mysuru and through conducting special camps. Data was collected as per the proforma prepared for the purpose of the study. *Nasya Karma* with *Nirgundi Taila* for 7 days, *Chopachinyadi Choorna* with *Shigru Patra Kwatha* as *Anupana* for 60 days were taken as intervention. The data was analysed using descriptive and inferential statistics. **Results:** The result on TSH value of 30 subjects after the intervention showed statistically non significant result with p value 0.067. Result on Zulewski's clinical score for hypothyroidism showed statistically highly significant result with p value 0.000. **Conclusion:** The intervention used in the study was more effective in reducing the symptomatology of Hypothyroidism, than normalizing the TSH value.

Key words: *Nirgundi Taila Nasya, Chopachinyadi Choorna, Shigrupatra Kwatha, Hypothyroidism.*

INTRODUCTION

Hypothyroidism is a very common disorder of thyroid gland, with reduced production of thyroid hormones,[1] it is the commonest functional disorder of the thyroid gland. Commonly seen symptoms are tiredness, weakness, dry skin, feeling cold, hair loss, difficulty in concentration and poor memory, constipation, weight gain with poor appetite etc. Prevalence of hypothyroidism in India is around 10.95% and females are more sufferers than males with ratio 6:1.[2]

In the present study hypothyroidism was analysed based on the *Dosha, Dushya, Sthana, Srotas* and *Agni*, by comparing the signs and symptoms of hypothyroidism. *Kapha* and *Vata* are the main *Dosha* involved in the pathology. Most of the symptoms of hypothyroidism are similar to that of *Kapha Vata Vriddhi, Pitta Kshaya* and *Agnimandya* which further leads to *Dhatvagni Mandhya, Rasa* and *Medha Dhatu Dushti*. The main organ involved is thyroid gland. It is located at the base of the neck which belongs to *Jatrurdhwa* as per Ayurveda.

Hence the intervention adopted in the study was *Nasya*, as *Nasya Karma* is the main treatment

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modality for *Jatrurdhvavyadhi. Chopachinyadi Choorna* (an indigenous formulation) having drugs of *Kapha Vatahara*, *Agnideepana*, *Pachana, Balya, Lekhana* and *Medhya* properties, was administered along with *Shigrupatra Kwatha* as *Anupana* which may help in reducing signs and symptoms of hypothyroidism.

OBJECTIVE OF THE STUDY

To evaluate the combined effect of *Nirgundi Taila Nasya* and *Chopachinyadi Choorna* with *Shigru Patra Kwatha* in the management of hypothyroidism.

MATERIALS AND METHODS

The materials used in the study were *Nirgundi Taila*[4] for *Nasyakarma* contains *Nirgundi Patra Swarasa, Langali Moola, Tila Taila*.[5,6]

The ingredients of *Chopachinyadi choorna* is mentioned in below table.

Table 1: Showing the ingredients of *Chopachinyadi Choorna*[7-14] along with *Shigrupatra*[15] *Kwatha* as *Shamanoushadhi.*

Vacha	1 part
Katuki	10 parts
Chopachini	30 parts
Ashwagandha	30 parts
Trikatu	30 parts
Kanchanara	30 parts

Source of drug and method of preparation

Nirgundi Taila, Chopachinyadi Choorna, Shigru Patra Kwatha Choorna were specifically prepared for the purpose of the study and procured from K.V.G Ayurveda Pharma and Research Centre, Sullia (a GMP certified company).

Methods

Method of collection of data

a) Study design

It was a single group open clinical trial with pre-post-test design

b) Sample size

A total of 34 subjects were registered for the study, there were 4 dropouts and the study was completed in 30 subjects.

The data was collected as per the case sheet pro forma designed for the study and informed written consent was taken.

c) Duration of study: 60 days

Inclusion criteria

1. Subjects belonging to age group of 18 to 50 years of all gender were included.
2. Subjects with the TSH value > 5.5 mIU/L to < 25 mIU/L
3. Subjects with elevated level of TSH which may or may not be associated with the reduced value of T_3 and T_4.
4. Both fresh and treated cases of hypothyroidism were included. A - Freshly detected and untreated cases of hypothyroidism. B - Established and treated cases of hypothyroidism also who were ready to discontinue the earlier medication.

A flush out period of about 10 days was allowed before the intervention.

Exclusion criteria

1. Subjects with congenital hypothyroidism, chronic history of hypothyroidism (>5 yrs.) and secondary hypothyroidism.
2. Subjects with any systemic illnesses which interrupt the present intervention.
3. Subjects who had undergone thyroid surgery.
4. Pregnant and lactating women were excluded.
5. Diagnosed cases of neoplastic conditions, toxic goitre was also excluded.

Diagnostic criteria

Objective criteria

Lab investigation: Thyroid profile with TSH >5.5 m IU/L to < 25mIU/L may or may not be associated with the reduced value of T_3 and T_4.

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Subjective criteria

Subjects who may or may not had any of these complaints along with raised TSH value.

Symptoms

1. Tiredness, weakness
2. Dry skin
3. Feeling colds
4. Hair loss
5. Difficulty in concentrating and poor memory
6. Constipation
7. Weight gain with poor appetite
8. Hoarse voice
9. Menorrhagia (later oligomenorrhea/amenorrhea)
10. Paraesthesia
11. Dyspnoea
12. Impaired hearing

Signs

13. Dry coarse skin
14. Cool peripheral extremities
15. Puffy face
16. Diffused alopecia
17. Bradycardia
18. Peripheral oedema
19. Delayed tendon reflex
20. Carpel tunnel syndrome

Assessment Criteria

1. The TSH value was assessed before and after intervention.
2. Zulewski's clinical score for hypothyroidism[16]

Table 2: Shows the Zulewski's clinical score for hypothyroidism.

On the basis of Symptoms	New score	
	Present	Absent
1. Diminished sweating	1	0
2. Hoarseness	1	0
3. Dry skin	1	0
4. Constipation	1	0
5. Weight increase	1	0
6. Paraesthesia	1	0
7. Impairment of hearing	1	0
Physical signs		
1. Coarse skin	1	0
2. Cold skin	1	0
3. Periorbital puffiness	1	0
4. Slow movements	1	0
5. Delayed ankle reflex	1	0

Sum of all symptoms and signs present: 12

A score of >5 points define hypothyroidism, while a score of 0-2 points defines euthyroidism.

Assessment schedule

In this study, total 2 assessments were done.

Pre-test assessment: Before starting the intervention (0^{th} day)

Post-test assessment: After the completion of intervention (61^{st} day)

Statistical methods

The results were analysed by using descriptive statistics and paired sample t test using SPSS for window software.

Investigation

Thyroid function test was done before and after intervention.

Intervention

Nasya Karma

Nasya Karma was carried out as per classical method, by instilling 2 *Bindu* (1ml) of *Nirgundi Taila* in each nostril for first 7 consecutive days of the intervention in the morning (between 8:00 am to 10:00 am) on empty stomach.

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Shamanoushadhi

Chopachinyadi Choorna

Subjects were administered 12 gm of *Chopachinyadi Choorna* and 50ml of *Shigrupatra Kwatha* per day in 2 equally divided doses i.e., 6 gm in each dose with 25ml of *Shigrupatra Kwatha* in each dose before food.

OBSERVATIONS

Age - Among 34 registered subjects 11 belonged to age group of 18 to 30 years, 13 were in the age group of 31 to 40 years, 10 were between the age group of 41 to 50 yrs.

Gender - Among 34 subjects 3 were male and 31 subjects were female.

Family history of hypothyroidism - 8 subjects had family history of hypothyroidism and 26 volunteers did not have family history of hypothyroidism.

Fresh and treated cases - 18 subjects were freshly treated and 16 were treated cases.

Mental stress - Among 34 subjects,17 subjects had history of mental stress.

***Agni* -** In 34 subjects, 19 were having *Mandagni*, 7 individuals had *Vishamagni* and 8 were having *Samagni*.

***Prakruti* -** Among 34 subjects, 2 were of *Vata Prakruti*, 17 were of *Kapha Vata Prakruti*, 6 subjects were of *Vatapitta Prakruti*, 2 were of *Kapha Prakruti,* 3 subjects had *Pitta Kapha Prakruti* and 4 were of *Vatakapha Prakruti.*

***Rasa Pradhanyata* -** Among 34 subjects, 10 were using *Madhura Rasa Ahara* in excess, *Madhura* and *Katu Rasa Ahara* was used in excess by 7 subjects, 5 volunteers were using *Katu* and *Tiktarasa* in excess, 5 subjects used *Katu Rasa* in excess ,1 subject preferred *Madhura, Amla, Lavana, Katu Rasa,* 1 subject used *Amla, Lavana, Katu, Tikta Rasa* in excess , 1 client used *Madhura, Lavana Rasa* in excess, 1 volunteer used *Lavana, Katu Rasa* in excess, 1 client used *Amla* and *Katu Rasaahara* more, 2 subjects used all the *Rasa* equally.

***Srotas* -** Among 34 registered subjects, all the 34 had the *Rasava Srotodushti Lakshana*, 5 individuals had *Raktavaha Srotodushti*, 20 subjects had *Medhavaha Srotodushti*, 30 had *Asthivaha Srotas* involvement, 9 subjects had *Majjavaha Srotodushti*, 15 had involvement of *Swedavaha Srotas*, 22 clients has *Pureeshavahasrotodushti* , 26 subjects had *Annavaha Srotodushti*, 9 had *Udaka Vaha Srotodushti* and 6 had involment of *Pranavaha Srotas*.

Body mass index (BMI) - Among the 34 clients, 15 had BMI between 18 to 24 Kg/m^2, 12 had BMI between 25 to 30 Kg/m^2, 5 had BMI between 31 to 35 Kg/m^2 and 2 had BMI between 36 to 40 Kg/m^2.

Observations on clinical features of hypothyroidism

Among 34 individuals, tiredness was present in 31 subjects, dry skin was present in 17, cold intolerance was present is 12, 31 subjects had hair loss, constipation was present in 27, weight gain was the complaint in 27 subjects, 26 had poor appetite, 6 had Menorrhagia, 4 had oligomenorrhea, 10 irregular menses, 4 did not had any menstrual disturbances, 10 had hoarseness of voice, muscle ache/stiffness was present in 20, puffiness of face or body was present in 12 individuals, difficulty in concentration and poor memory was present in 24 subjects.

RESULTS

A total of 34 subjects were registered for the study, there were 4 dropouts. The results were obtained by assessing 30 subjects who have completed the study.

Result on TSH Value

Among 30 subjects, before intervention 17 (56.7%) subjects had TSH value between 5.5 to 10.5 m IU/L, 6 (20%) clients had TSH value between 10.6 to 15.5 m IU/L, 3 (10%) had TSH value between 15.6 to 20.5 m IU/L, 4(13.3%) individuals had TSH value between 20.6 to 25 m IU/L.

After intervention 13 (43.33%) subjects had TSH value between 5.5 to 10.5 m IU/L, 8 (26.7%) had TSH value between 10.6 to 15.5 m IU/L, 5 (16.7%) had TSH value between 15.6 to 20.5 m IU/L, 3 (10%) had TSH value

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between 20.6 to 25 m IU/L and 1(3.33%) Subject had TSH value more than 25 m IU/L

Hence the result on TSH value of 30 subjects before and after the intervention showed statistically non-significant result with p value 0 .067.

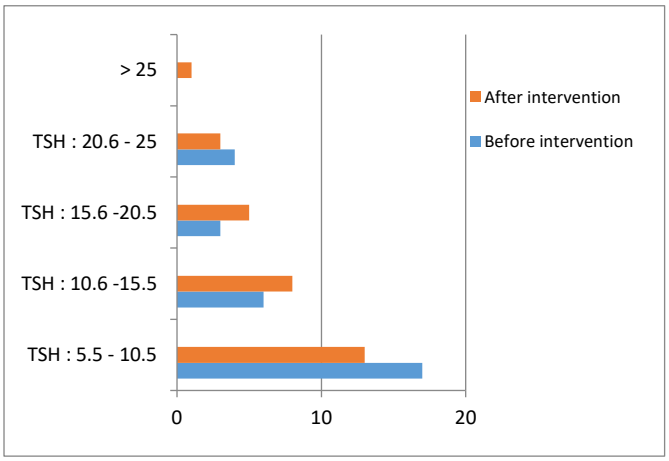
Table 3: Shows TSH value before and intervention.

TSH Range (m IU/L)	Before Intervention	After Intervention
5.5 - 10.5	17 (56.7%)	13 (43.33%)
10.6 - 15.5	6 (20%)	8 (26.7%)
15.6 - 20.5	3 (10%)	5 (16.7%)
20.6 - 25	4 (13.3%)	3 (10%)
>25	0	1 (3.33%)

Paired sample t test		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	TSH_bef	11.7453	30	5.30563	0.96867
	TSH_aft	14.3510	30	9.46573	1.72820

Paired Differences	Mean	Std.Deviation	t	Df	Sig.(2-tailed)
Pair 1 score bef – score aft	-2.60567	7.51368	-1.899	29	0.067

Illustration 1: TSH Value Distribution before and after intervention.



Result on Zulewski's clinical score for Hypothyroidism

Among 30 subjects, before intervention 3(10%) had score between 0-2, 11 (36.7%) had score 3-5, 16 (53.33%) had score >5.

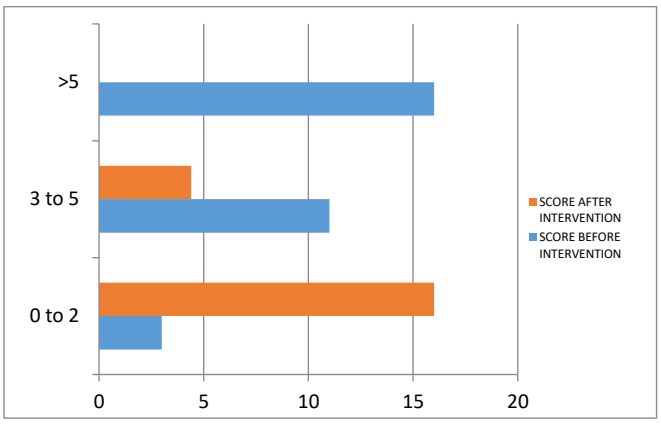
After intervention, 16 (53.33%) individuals had score between 0-2, 14 (46.7%) had score between 3-5.

Table 4: Shows Zulewski's Clinical Score before and after intervention.

Score	Before Intervention	After Intervention
0-2	3 (10%)	16 (53.33%)
3-5	11 (36.7%)	14 (46.7%)
>5	16 (53.33%)	0

The data obtained from the 30 subjects, based on the Zulewski's Clinical Score for Hypothyroidism before and after the intervention showed statistically highly significant result with p value 0.000.

Illustration 2: Zulewski's Clinical Score before and after intervention.



Paired sample t test		Mean	N	Std. Deviation	Std. Error Mean
Pair 1	score_bef	5.2000	30	1.84578	0.33699
	score_aft	2.4000	30	1.27577	0.23292

Paired Differences	Mean	Std.Deviation	T	Df	Sig.(2-tailed)
Pair 1 score bef – score aft	2.80000	1.60602	9.549	29	0.000

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DISCUSSION

Among the 30 subjects, in 12 individuals TSH value has been reduced from 0.2 to 6 m IU/L after intervention. It was observed that in 18 subjects TSH level was increased from 3 to 30 m IU/L after intervention. In none of the subjects TSH value was reduced to normal range after intervention. The intervention used in the present study were effective in reducing the symptoms of hypothyroidism like constipation, hoarseness, reduced sweating, dry skin, coarse skin, cold skin and periorbital puffiness. 1 to 3 kg of weight loss was found in few subjects.

Nirgundi Taila Nasya and *Chopachinyadi Choorna* with *Shigru Patra Kwatha Anupana* were effective in reducing the clinical features of hypothyroidism but not effective in normalizing the TSH value.

Probable mode of action of *Nasya Karma*

In the present study *Shirovirechana Nasya* was taken as one of the interventions based on the *Adhishtana* and *Dosha Pradhanyata*.

In hypothyroidism the main pathology is present in thyroid gland, which is situated in the *Urdhvajatru*. Predominant *Dosha* involved here are *Kapha* and *Vata*. *Nasya* is said to be the best treatment for *Urdhvajatru Vikara*. *Shirovirechana* type of *Nasya* is helpful in alleviating the *Kaphaja Urdhvajatrugata Vikara*.

The nasal route of administration offers many advantages for local and systemic drug delivery.

The nasal route presents a large surface area for drug deposition and permeation. Good vascularisation of the nasal epithelium facilitates the rapid absorption of drugs into the systemic circulation and hence provides a rapid onset of drug action. Furthermore, nasal mucosa has lower enzymatic activity than that of GI tract.

Therefore, the nasal route is convenient for the administration of drugs. Drugs administered by the nasal route bypass first-pass hepatic metabolism and are absorbed directly into the systemic circulation, the bioavailability of some drugs given by this route is higher than after oral administration.[17]

Probable reasons for non-significant result in normalizing the TSH value.

Nasya was selected as one of the interventions, with an intention that it will help in *Sampraptivighatana*, but the pattern of *Nasya* chosen in this study might not be suitable for managing hormonal imbalances, as it requires continuous monitoring to normalize the hormone levels.

Apart from the study it has been observed that, one subject who has advised for *Pratimarsha Nasya* showed better reduction in the TSH value compared to the study subjects. Hence it is suggested that *Pratimarsha* type of *Nasya* could have been better.

Limitation to identify the specific cause of hypothyroidism like either autoimmunity/iodine deficiency / iatrogenic / infiltrative disorders etc; may be one of the reasons for not getting significant result in TSH value.

CONCLUSION

Hypothyroidism is a hypo metabolic state resulting from the deficiency of thyroid hormones. It is not a single disease entity, but involves multiple systems. It is a condition involving *Agnimandhya* both at *Jataragni* and *Dhatvagni* level, along with *Kapha*, *Vata Vriddhi*, *Pitta Kshaya* and *Rasavaha Srotodushti*. To stabilize this condition a study attempt was done by administering *Nirgundi Taila Nasya*, *Chopachinyadi Choorna* with *Shigrupatra Kwatha* as *Anupana*. After the completion of intervention for 60 days, there was statistically non-significant result in normalizing the TSH levels, with p value > 0.069. However, the intervention used in the present study relieved the signs and symptoms of hypothyroidism very effectively which is proved by statistically highly significant result with p value 0.000.

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