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A Clinical Study To Evaluate The Combined Effect Of Nirgundi Taila Nasya Followed By Gomutra Haritaki In The Management Of Hypothyroidism

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ABSTRACT:

Ayurveda, an ancient and the first systemic medical science ever evolvedthroughout the globe emphasizes on physical and mental fitness with prevention. Hypothyroidism refers to deficiency of thyroid hormone caused due to various reasons. The Concept of Hypothyroidism is directly not mentioned in classical textsbut it can be correlate with various topics mentioned by Acharyas such as Galaganda, concept of Dhatwagni, Samprati of Medoroga and much more. Among them it is sincere attempt to evaluate the concept of Hypothyroidism with Galaganda. Also this research carried out to evaluate the efficacy of of Nirgundi Taila Nasya followed by Gomutra Haritaki in the management of Hypothyroidism. **Aims & objectives:** To evaluate the combined effect of *Nirgundi Taila Nasya* followed by *Gomutra Haritaki* in management of *Hypothyroidism*.

Materials and Methods: 30 patients of Hypothyroidism will be selected randomly

from and given Nirgundi Taila Nasya followed by Gomutra Haritaki. .

8 drops of Nirgundi Taila was instilled in each nostril for 7 days and Haritaki churna of 2 gm thrice a day along with Gomutraarka of 8 ml was given for 23 days after shodana krama.

Results: Complete remission was shown by 12(65%) patients and Marked improvement was shown by 18(35%) patients. At the end of treatment No patient remain unchanged.

Conclusion: Thus the Nirgundi Taila Nasya followed by Gomutra Haritaki proved that effective in combating the disease Hypothyroidism.

Key words: Galaganda, Hypothyroidism, Nirgundi Taila Nasya, Gomutra Haritaki

INTRODUCTION:

Hypothyroidism or thyroid hormone deficiency due to abnormality in the thyroid gland is the most common endocrine disease. Hypothyroidism is a hypo metabolic clinical state resulting from inadequate production of thyroid hormones for prolonged periods. Rarely does it occur from resistance of the peripheral tissues to the effects of thyroid hormones¹. The condition is associated with decreased production of T3 - T4 and increased production of TSH, Symptoms are intolerance to cold, receding hairline, facial and eyelid edema, dull- blank expression, extreme fatigue, thick tongue, slow speech, anorexia, brittle nails and hair, hair loss, apathy, lethargy, dry skin, muscle aches and weakness, constipation, weight gain, bradycardia^{2,3}. In India 42 million people are suffering from thyroid disorders, out of which Hypothyroidism is the most common⁴. By using the nasya, it is possible to treat only the tertiary Hypothyroidism, where the hypothalamus fails to produce sufficient thyrotropin releasing hormone⁵.

In Ayurveda there is no direct mention of thyroid gland, but a disease by the name Galaganda, characterized by neck swelling, is well known. The symptoms of Galaganda and Hypothyroidism are vaguely similar. According to Acharya Vagabhata Kapha associated Pitta dushti with vitiation of Vata due to Margavarna and predominantly Rasa-vaha, Medo-vaha and Mamsa-vaha Srotodushti can be considered as cause of this disease.⁶ Lakshanas of Galganda is explained in Sushruta Samhita Nidana 11th chapter, Yogaratnakara nidan 11th chapter and Samprapti in Charaka Samhita chikitsa 12th chapter.

If the aggravated kapha is located outside the throat, it causes swelling eventually, called as Galaganda⁷. The signs and symptoms of hypothyroidism nearly relate to a condition called as Galaganda and some of the kaphajananatmaja vyadhis⁸. The Sthana of the thyroid gland being urdhwajatru, which is a kaphasthana⁹, for the elimination of kapha, Shiro Virechna Nasya has been described by Acharyas¹⁰.

Hence the intervention adopted in this study was *Nasya*, so *Nirgundi Taila Nasya Karma¹¹* is the main treatment modality for Jatrurdhvavyadhi followed by *Gomutra¹² Haritaki¹³* which is having Katu-Tikta-Kashaya Rasa Pradhana and Ushna Veerya, act as Kapha hara and helps to breakdown the pathology of Hypothyroidism.

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AIMS AND OBJECTIVES

• To evaluate the combined effect of *Nirgundi Taila Nasya* followed by *Gomutra Haritaki* in management of *Hypothyroidism*.

Hypothesis

- Null Hypothesis (H₀): There is no significant effect of *Nirgundi Taila Nasya* followed by *Gomutra Haritaki* in the management of *Hypothyroidism*.
- Alternate Hypothesis (H₁): There is significant effect of *Nirgundi Taila Nasya* followed by *Gomutra Haritaki* in the management of *Hypothyroidism*.

METHODOLOGY

Source of Data Clinical Sources

Minimum 30 patients of Hypothyroidism were selected randomly from the OPD, IPD and by conducting the special camps in Department of Post Graduate Studies in Panchakarma, Bhagawan Mahaveer Jain Ayurvedic Medical College, Hospital & PG Centre Gajendragad.

Literary: All the available data on Galaganda was collected from Ayurvedic and Modern textbooks, journals and websites.

Drug source: Raw materials were collected from local market after proper identification. Medicines required for the treatment were prepared in Bhagawan Mahaveer Jain Ayurvedic Medical College pharmacy.

Study Design:

• An open observational clinical study.

Methods Of Collection Of Data

A special Proforma was prepared with all points of history taking, physical examination was carried out as mentioned in allied sciences. Selected patients were subjected to detailed history and thorough clinical examination.

Inclusion Criteria

- 1. Patients who are diagnosed with Hypothyroidism with or without medicine and with or without washout period.
- 2. TSH value upto 100mIU/ml.
- 3. Patients who are under Thyroxine Sodium Medication.
- 4. Patients with chronicity of the disease of 1-10 years.
- 5. Patients between the age of 18 to 50 years.
- 6. Patients who are fit for Shirovirechana Karma.

Exclusion Criteria

- 1. Diagnosed cases of Cardiac disease, Congenital anomalies & Ischemic heartdisease.
- 2. Patients suffering from Congenital hypothyroidism, Carcinoma of the thyroid gland, Thyroid nodules, Goiter, Thyroiditis, Myxedema, Thyrotoxicosis.
- 3. Pregnant and lactating women.
- 4. Those who are not fit for ShirovirechanaKarma.
- 5. Patients with esophageal varices.
- 6. Patients diagnosed with uncontrolled diabetes and hypertension.

Intervention:

^{1.} Shirovirechana Karma

1	Purva Karma	Sthanika Mukha Abhyanga followed by
		Bashpa Sweda
2	Pradhana	8 drops of Nirgundi Taila ⁹ is instilled in Done for 7days
	Karma	each nostril.
3	Paschatha	Kavala with TriphalaKashaya followed
	Karma	by Dhumapana with HaridraKhanda.

2. GomutraHaritaki:

Source of drug for Gomutra Haritaki:

- The Drugs are Gomutraarka and Haritaki churna which were collected from BMJ AMC Pharmacy, Gajendragad.
- The Dosage of the drug was 6 gm/day in 3 divided doses
- Haritaki churna of 2 grms¹² was giving along with Gomutraarka of 8 ml¹³.
- The treatment duration of Nasya was decided as per shuddi of patient during Nasya and Gomutra Haritaki was giving for 23 days after shodana krama.

Diagnostic Criteria

The diagnosis of the disease is mainly based on the signs and symptoms mentioned in modern text¹⁴ and classical texts^{15, 16} as follows:-

- Weight gain
- Cold intolerance
- Fatigue
- Somnolence
- Constipation
- Delayed tendon reflexes

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- Aches and pains
- Depression
- Dry skin
- Dry hair
- Menstrual irregularities
- Mushkavat lamba gala
- Atinidra
- Vahnimandya

Assessment Criteria:

Reduction in the signs and symptoms of Hypothyroidism was observed before and after the treatment depending upon the clinical features and assessment of TSH values.

1. Subjective Parameters:

- Nibaddha Shwayathu (Neck Swelling)
- Rasa-Aasyata (changes in taste)
- Varna Parivartan (changes in colour)
- Gala-Talu Parivartan (Throat and neck changes)
- Ruja (pain at site of swelling)
- Weight gain
- Muscle cramps
- Dry & coarse skin
- Fatigue

2. Objective parameter:

TSH Level

Grading for Assessment of the Subjective parameter

The Hypothyroidism will assessed with 0 to 3 gradations from mild to severe is mentioned bellow table

SI.	Subjective Criteria	Gradation	Score	
No.				
		Nibaddha Shwayathu (Neck Swelling)	0	
	Angamarda (body	No swelling	1	
1	ache)	Mild swelling (Pal-pable but not visible)	2	
		Nibaddha Shwayathu (Neck Swelling)	3	
		No changes in Rasa-Aasyata	0	
	Rasa-Aasyata	Snigdhasyata (only coated tongue)	1	

	(changes in taste)	Madhuryamasyata (Taste sense changes	2
		toward sweetness)	
		Vairasyamasyata (tastelessness)	3
	Varna Parivartar	No changes in colour	0
	(changes in colour)	Mild discolouration over affected site	1
		Moderate visible colour chang-es towards <i>Shya-va/Aruna/Pandu</i>	2
		Complete change of colour of affected site	3
		No changes	0
	Gala-Talu Parivartan	Mild difficulty like dysphagia	1
4	(Throatand neck changes)	Moderate difficulty like <i>Talu-galaprashosh</i> (sore throat), <i>Jantogaleanushabdam</i> (slurred speech)	2
		Severe difficulty like severe Dysphagia, Aphagia	3
		No pain	0
	Ruja(pain at site of	Only Kndu (itching) but no Ruja (pain)	1
5	swelling)	<i>Kandu</i> (Itching) with Moderate or tolerable <i>Ruja</i> (pain)	2
		severe Kandu (Itch-ing) and Severe pain	3
		(Ruja) both	
6		BMI <20	0
	Weight gain	BMI 20-25	
		BMI 25-30	
		BMI 30-35	3
		Not present	0
7	Muscle cramps	Once in a week	1
		Twice / Thrice a week	2
		Continuously present	3
		No dryness	0
		Dryness after bath only	1
8	Dry& coarse skin	Dryness for whole day but re-lieved by oil application	2
		Dryness not even relieved by oil appli- cation	3
		No fatigue	0
9	Fatigue	Mild fatigue	1
,	1 411-540	Moderate fatigue	2
		Severe fatigue	3

Grading for Assessment of the Objective Parameter

		0.30- 6.00 IU/ml	0
1	TSH level	6.00-7.00 IU/ml	1
1		7.00-8.00 IU/ml	2
		>8.00 IU/ml	3

RESULTS:

Table: Effect of the treatment on Subjective Criteria

	Mean			%	Paired 't' test			
Symptom	BT	AT	Diff.	Relief	SD	SE	ʻt'	Р
Angamarda	2.00	0.63	1.36	68	0.49	0.08	15.27	< 0.05
Rasa-Aasyata	2.20	0.60	1.60	73	0.49	0.09	17.58	< 0.05
Varna	2.10	0 <mark>.53</mark>	1.57	75	0.50	0.09	1.02	< 0.05
Parivartan			~ 1					
Gala-Talu	2.00	0.63	1.37	68	0.49	0.08	15.27	< 0.05
Parivartan								
Ruja	2.10	0.60	1.50	71	0.62	0.11	13.04	< 0.05
Weight gain	2.13	0.66	1.46	69	0.50	0.09	15.83	< 0.05
Muscle cramps	1.73	0.50	1.23	71	0.43	0.07	15.70	< 0.05
Dry & coarse	1.83	0.50	1.33	73	0.47	0.08	15.23	< 0.05
skin				10				C.Y
Fatigue	2.10	0.56	1.54	73	0.57	0.10	14.69	< 0.05

- Angamarda (body ache): There was a significant changes have been seen in after treatment in all the patients. Mean BT in was 2.00 which was reduced to 0.63 and 68% relief was seen in the symptom. Here S.D is 0.49, also 'P' value is less than 0.05. Hence, the treatment is significantly effective on the symptom Angamarda.
- Rasa-Aasyata (changes in taste): There was significant changes have been seen in after treatment in all the patients. Mean BT in was 2.20 which was reduced to 0.60 and 73% relief was seen in the symptom. Here S.D is 0.49, also 'P' value is less than 0.05. Hence, the treatment is significantly effective on the symptom Rasa-Aasyata.
- Varna Parivartan (changes in colour): There was significant changes have been seen in after treatment in all the patients. Mean BT in was 2.10 which was reduced to 0.53 and 75% relief was seen in the symptom. Here S.D is 0.50, also 'P' value is less than 0.05. Hence, the treatment is significantly effective on the symptom Varna Parivartan.

- Gala-Talu Parivartan (Throat and neck changes): There was a significant change have been seen in after treatment in all the patients. Mean BT in was 2.00 which was reduced to 0.63 and 68% relief was seen in the symptom. Here S.D is 0.49, also 'P' value is less than 0.05. Hence, the treatment is significantly effective on the symptom Gala-Talu Parivartan.
- Ruja (pain at site of swelling): There was a significant change have been seen in after treatment in all the patients. Mean BT in was 2.10 which was reduced to 0.60 and 71% relief was seen in the symptom. Here S.D is 0.62, also 'P' value is less than 0.05. Hence, the treatment is significantly effective on the symptom Ruja.
- Weight gain: There was significant changes have been seen in after treatment in all the patients. Mean BT in was 2.13 which was reduced to 0.66 and 69& relief was seen in the symptom. Here S.D is 0.50, also 'P' value is less than 0.05. Hence, the treatment is significantly effective on the symptom weight gain.
- Muscle cramps: There was a significant change have been seen in after treatment in all the patients. Mean BT in was 1.73 which was reduced to 0.50 and 71% relief was seen in the symptom. Here S.D is 0.43, also 'P' value is less than 0.05. Hence, the treatment is significantly effective on the symptom muscle cramps.
- Dry & coarse skin: There was a significant change have been seen in after treatment in all the patients. Mean BT in was 1.83 which was reduced to 0.50 and 73% relief was seen in the symptom. Here S.D is 0.47, also 'P' value is less than 0.05. Hence, the treatment is significantly effective on the symptom dry & coarse skin.
- Fatigue: There was a significant change have been seen in after treatment in all the patients. Mean BT in was 2.10 which was reduced to 0.56 and 73% relief was seen in the symptom. Here S.D is 0.57, also 'P' value is less than 0.05. Hence, the treatment is significantly effective on the symptom Fatigue.

Symptom	Mean			%	Pa	Р		
Symptom	BT	AT	Diff.	Relief	SD	SE	't'	
TSH level	2.03	0.53	1.50	74	0.50	0.09	16.15	< 0.05

Table: Effect of the treatment on Objective Parameter

TSH level: There was a significant change have been seen in after treatment in all the patients in TSH level. Mean BT in was 2.03 which was reduced to 0.53 and 74% relief was seen in the symptom. Here S.D is 0.50, also 'P' value is less than 0.05. Hence, the treatment is significantly effective on the symptom TSH level.

DISCUSSION:

In Ayurveda the disorder of thyroid gland is described under the title of Galganda. If we see the Nanatatmaja Kapha Roga and Rasaja as well as Meda Dhatu Vikara, most of them are present as the symptoms of hypothyroidism.

Dhatvagni Madhya is also a major feature in this disease. Because of its slow onset, hypothyroidism is categorised as chronic disease where involved Dosha are at its maximum level. The signs and symptoms of hypothyroidism mentioned in modern medicine show that Kapha Dosha play a major role in this disease, secondly the involvement of Vatadosha is also there. From the Dhahtu aspect, it can be said that mainly the Dushti of Rasadhatu and Medadhatu is seen in hypothyroidism. It satisfies both, involvement of thyroid gland as well as symptom complex of hypothyroidism.

Ayurvedic management for thyroid disease is a holistic and supportive therapy that aims to correct the Doshaj imbalance as well as normalise the contributing factors. At metabolism level Deepana, Pacahana, Ushna, Teekshna, Sukshma, Lekhana drugs which pep-up body metabolism is recommended. It includes the recommendation of herbal medicines principally for Dosha balance and to some extent specifically to promote thyroid function, dietary guidance, and lifestyle recommendations.

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.

 Nirgundi taila having drugs with Madhura, Katu, Tikta Rasa, Laghu Ruksha Guna, With Ushna virya and Katu vipaka with vatakaphahara, Krimihara, Vranaropana, Medoghna properties helps to breakdown the samprapti of Galaganda.

Probable mode of action of Gomutra Haritaki

Gomuta is also has karma of Kapha Vaathar in nature. It also does Lekhan karma by its Rasa-Guna-Virya and Vipaka. With the help of Amla Rasa it promotes Agni deepan function

 Haritaki with Pancharasa pradana, Laghu Ruksha guna, Ushna virya, Tridosha shamaka, does karmas like Shothahara, Krimighna, Kaphahara, Vedanasthapana. Above drugs combinely works as Kaphvaathar, Lekhan, Medhya, Medoghna as well as Agni-Deepak which breaks down the Samprapti of Galaganda.

CONCLUSION

- In this study 30 patients were treated with Nirgundi Taila Shirovirechana/Nasya followed by Gomutra Haritaki, maximum patients were from the age group 31-40, 90% patients were female, maximum i.e. 80% patients were married, maximum i.e. are literate, 40% patients had mandagni.
- Complete remission was shown by 12(65%) patients and Marked improvement was shown by 18(35%) patients. At the end of treatment No patient remain unchanged.
- Thus the Nirgundi Taila Nasya followed by Gomutra Haritaki proved to be effective in combating the disease Hypothyroidism.
- There is a need to study on a large scale sample and on various entities for more appropriate result, because present research work is carried out on a small size sample with limited study duration

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