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A CLINICAL STUDY TO EVALUATE THE EFFICACY OF *TRIPHALADYA GUGGULU* ALONG WITH *PANCHKOL PHANT* IN THE MANAGEMENT OF *AGNIMANDHYA* IN THE CONTEXT OF HYPOTHYROIDISM

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ABSTRACT

The metabolic activities of the body done by thyroid hormones can be compared to functions of *Dhatvagnis*. On closely analysing, the sign and symptoms of primary hypothyroidism seems to correlate with hypo functioning of *Jathragni* which effects *Dhatvagni*, that is basic factor for occurrence of the hypothyroidism. **Materials and Methods:** 30 eligible hypothyroid patients with serum thyroid‑stimulating hormone > 4.2 to 8 uIu/ml and serum T3 and T4 lower than their respective normal range were selected. This study was undertaken to evaluate the combine effect of *Pathya Aahar* and *Vihara* along with *Triphaladya Guggulu* and *Panchkol Phant* in patients for period of 2 months. Patients were advised to discontinue any medicine they might be taking for the management of hypothyroidism to assess the unbiased effect of therapies. **Results:** In the study, 30% of patients showed complete remission, a marked positive response was observed in 33%, a moderate positive response was seen in 30% while mild relief was found in 7%, and 0% of patients were unchanged. **Conclusion:** *Triphladya Guggulu* and *Panchkol Phant* are effective in the management of hypothyroidism.

KEYWORDS: Thyroid hormones, *Dhatvagnis*, *Jathragni*, Hypothyroidism.

INTRODUCTION

Hypothyroidism is one of the most common diseases in worldwide. Thyroid diseases affect an estimated 200 million people worldwide. An estimated 40% of the world's population– some 2.8 thousand million people are at risk of iodine deficiency, some nutrient that is essential for the production of thyroid hormones.[1] In India, more than 10 million cases per year of hypothyroidism is found. The prevalence of hypothyroidism is high, affecting approximately one in 10 adults in the study population. Hypothyroidism affects up to 5% of the general population, with further estimated 5% being undiagnosed. Over 99% of affected patients suffer from primary hypothyroidism.[2] Now a days, very common ages affected from hypothyroidism in India are 19-60+ years. According to a survey, North India recorded the maximum cases of hypothyroidism in comparison with the south and west zones of India.[3] It mostly affects the young females then males, but clinical symptoms arise in the middle-aged female gender. Understanding hypothyroidism through an *Ayurvedic* lens involves exploring the interplay of various factors such as diet, lifestyle, stress, and environmental influences. In the light of *Ayurvedic* principles, it is understood that the pathogenesis and manifestation of hypothyroidism occur due to dysfunction of *Agni*. The metabolic activities of the body done by thyroid hormone can be compared to functions of *Dhatvagnis*. According to *Acharya Charak*, *Agni* is considered to be of thirteen types: *Jatharagni*, *7 Dhatvagni*, and *5 Bhutagni*. Among these types, *Jatharagni* is considered to be the best. It nourishes the remaining 12 *Agni* by staying in its place. When it is slow or distorted, the *Dhatvagni* and *Bhutagni* also become slow or distorted.[4] When the *Vata*, *Pitta*, and *Kapha Doshas* remain in normal states with *Jatharagni*, then it digests the food for better health, nourishment, age, and strength[5]. But slow or distorted conditions of *Jatharahni* starts with an improper diet and a sedentary lifestyle, which are now very common in modern society. Improper diet, characterized by the consumption of heavy (*Guru*), cold (*Sheetha*), excessively sweet (*Ati-Madhur*), excessively oily (*Ati-Snighdha*), and *Kapha*-aggravating foods, leads to the aggravation of *Kapha Dosha*. The increased amount of *Kapha* impairs the *Jatharagni* (digestive fire), leading to the formation of *Ama* (toxins). As *Dhatvagni* (tissue

metabolism) depends on *Jatharagni*, its impairment further exacerbates the imbalance.[6] So, impairment of *Dhatvagni* takes place in due course of time. If the vitiation of *Dhatvagni* is not treated properly, it can reach up to genetic levels (*Sukra* and *Artava*), which may give rise to congenital hypothyroidism (Cretinism). The primary objective of this study is to investigate the therapeutic efficacy and safety of *Ayurvedic* treatments, specifically *Triphaladhi Guggulu* with *Panchkola Phant*, in individuals with hypothyroidism.

AIMS AND OBJECTIVES

1. To evaluate the role of *Triphalaadya Guggulu* along with *Panchkol Phant* in the management of hypothyroidism.
2. To find out an effective, economical, easily available, curative therapy for the treatment of hypothyroidism.

MATERIAL AND METHODS

Selection of patients: A total of 30 patients suffering from hypothyroidism were selected from the outdoor patient department (OPD) and indoor patient department (IPD) of Kayachikitsa, DBACH, Mandi Gobindgarh, irrespective of their religion, Caste, and occupation, etc. Ethical clearance was obtained from the institutional ethics committee via DBACH/1034/2022-23 dated 18 July 2022. This clinical trial was registered with the Clinical Trials Registry of India (CTRI) prior to participant enrolment. The registration number is CTRI/2023/04/051443. Informed written consent in language suitable to the patients was obtained from all enrolled participants. A detailed history regarding family history, past illness, and clinical findings pertaining to *Ashtavidha and Dashvidha Pariksha*.

Inclusion Criteria

- Diagnosed cases of hypothyroidism on the basis of serum TSH, T3, and T4 levels-

TSH level	> 4.2 to 8 uIu/ml
T4 level	normal or less than normal value (4.5–12.5 µg/dl)
T3 level	normal or less than normal value. (80–220 ng/dl).

- Patients having clinical features of hypothyroidism- Puffiness of the face and eyelids, peripheral oedema, dry coarse skin, breathlessness, constipation, weakness, lethargy, fatigue, muscle ache, menstrual abnormality, hair loss, age 18-45 years (female).

Exclusion Criteria:

- Patient with renal disease,
- post myocardial infarction or congestive heart failure,
- Patient on treatment of lipid-lowering drugs or 3 months prior history of taking lipid-lowering drugs.
- Pregnant women,
- Patient with acute medical illness,
- Patient with concomitant inflammatory disease,
- Patient with hypothalamic-pituitary disorder
- Active malignant disease
- Phenytoin, carbamazepine, sertraline, furosemide and non-steroidal anti- inflammatory drugs.

Other laboratory investigations:

Routine haematological investigation (complete blood count and erythrocyte sedimentation rate), Lipid profile (Serum cholesterol, Serum Triglyceride, Serum Low Density lipoproteins, Serum very LDL, serum high-density lipoprotein). These investigations were carried out before and after the treatment.

Drugs and Dosage

The following medications were administered to the patients for a period of 2 months.

1. *Triphaladya Guggulu* 500 mg twice daily after meal with *Panchkol Phanta*.
2. *Panchkol Phant*– 5grams twice a day after meal (patients were advised 10 grams of coarse powder of *Panchkol* added to 150 ml of boiled water). After it cooled down slightly (usually 15 mints), the powder was well meshed, and the liquid will be filtered at last).

The trial drugs were procured from Pharmacy, DBAC&H.

METHODOLOGY

All the patients were advised to discontinue any drug they might be taking for the management of hypothyroidism to assess the unbiased effect of therapies. The drug was withdrawn 2 weeks before including the patient in the clinical trial. Patients were advised, as per *Ayurvedic* fundamental principles, is *Nidana Parivarjana* means avoiding the causative factors, which are the root causes for any disease to occur, and advised to indulge in *Pathyas* like light diet and *Yoga Asana* to maintain thyroid health. The patients were advised to take adequate amount of each nutrient (1000 kcal/day), use of *Rakta Shali*, *Rohita Matsya*, *Saindhava Lavan*, *Go-Dhughda*, *Ghrita*, *Yava*, *Mudga*, *Patola*, *Shighru*, *Trijataka* (*Twak Ela* and *Patra*), *Lashuna*, *Karavellaka*, *Madhu*, Oatmeal and Quina, as per their choice. The patients were also advised to practice *yoga* and *Pranayama*. In *yoga*, especially- *Sarvangasana* (Shoulder Stand), *Marjaryasana* (Cat-Cow Pose), *Matsyasana* (Fish Pose), *Ustrasana* (Camel Pose), *Bhujangasana* (Cobra Pose), *Setubandhasana* (Bridge Pose). In *Paranayam*, especially – *Brahmari* (Bumble Bee Breath), *Anulom-Viloma* (Forceful alternate nostril breathing), *Kapalbhati*. Patients were also advised restraining from unhealthy food habits, like avoiding

eating large amounts of raw cruciferous vegetables, gluten, and ultra-processed food. Vegetable that contains goitrogens (cabbage, broccoli, cauliflower, kale) and Nuts-seeds like millet, pine nuts, peanuts were also restricted. Sleep during the daytime and excessive amounts were prohibited during the trial period.

Criteria for assessment

1. Improvement observed in patients was assessed mainly on the basis of relief in percentage change in the presenting complaints of hypothyroidism on the basis of scoring pattern decided in a previous study.[7]
2. Thyroid profile (Serum TSH, T3 and T4).
3. BMI

Follow-up: follow-up was carried out at 15 days interval for the duration of 8 weeks.

RESULT

Table 1: Symptoms wise distribution of patient with effect of treatment in percentage

Symptoms	No. of Patients	BT	AT	Relief (%)
Puffiness	25	38	4	89.47%
Oedema	15	23	3	86.95%
Dry & Coarse	17	22	2	90.90%
Breathlessness	16	28	5	82.14%
Constipation	18	31	4	87.09%
Weakness	17	23	3	86.95%
Lethargy	18	24	3	87.5%
Fatigue	9	18	3	83.33%
Muscle ache	12	21	2	90.47%
Duration of menstrual cycle	13	22	3	86.36%
Interval between two cycles	12	19	1	94.73%
Hair fall	18	28	6	78.57%

The total effect of treatment on the symptoms of each patient was evaluated before and after completion of the treatment. The relief percentage in individual symptoms of hypothyroidism revealed a better therapeutic efficacy of treatment.

Table 2: Effect of therapy on subjective parameter.

Symptoms	n	Mean		Mean Diff.	SD	SE	*'t'*	P
		BT	AT					
Puffiness	25	1.26	0.58	0.68	0.48	0.09	3.07	<0.001
Oedema	15	1.26	0.6	0.66	0.46	0.12	5.09	<0.001
Dry & Coarse Skin	17	1.14	0.55	0.59	0.41	0.1	3.77	<0.001
Breathlessness	16	1.37	0.65	0.72	0.5	0.12	5.6	<0.001
Constipation	18	1.36	0.61	0.75	0.53	0.125	5.36	<0.001
Weakness	17	1.17	0.58	0.59	0.41	0.101	3.86	<0.001
Lethargy	18	1.16	0.58	0.58	0.33	0.09	4.81	<0.001
Fatigue	9	1.5	0.66	0.84	0.59	0.19	6.1	<0.001
Muscle ache	12	1.37	0.58	0.79	0.55	0.16	3.92	<0.001
Duration of menstrual cycle	13	1.34	0.61	0.73	0.51	0.14	5.81	<0.001
Interval between two cycles	12	1.29	0.54	0.75	0.53	0.15	5.9	<0.001
Hair fall	18	1.27	0.66	0.61	0.43	0.1	3.56	<0.001

The results were significant in almost all the signs and symptoms of hypothyroidism. Highly significant improvement ($P < 0.001$) was observed on all the complaints, such as puffiness oedema, and dry coarse skin, etc.

Table 3: Effect of therapy on S. TSH and body mass index.

Parameters	n	BT	AT	Mean		Mean BT-AT	RELIEF %	SD	SE	't'	P
				BT	AT						
S.TSH	30	197.4	53.67	3.79	1.39	2.4	72.81 %	1.69	0.30	4.08	<0.001
BMI	30	51	34	13.5	1.06	0.29	66.66%	0.2	0.03	5.2	<0.001

There were significant changes seen in S.TSH value; mean B.T. was 3.79, which was reduced to 1.39. Here S.D. is 1.69; the calculated "t" value is greater than the two-tailed table 't' value at the level of $P < 0.001$. There

was a significant decrease ($P < 0.01$) in body mass index by 66.66%, respectively.

Table 4: Overall effect of therapy.

Overall effect	No. of patients	Percentage
Complete remission (100 % relief)	9	30%
Markedly improved (75-99% relief)	10	33%
Moderately improved (50-74% relief)	9	30%
Mild improvement (25 – 49%)	2	7%
Unchanged (<25% relief)	0	0%

In 30 patients, 30% of patients showed complete remission, marked relief was observed in 33%, moderate relief was seen in 30%, while mild relief was found in 7%, and 0% of patients were unchanged. Highly significant results were observed in subjective and objective parameters.

DISCUSSION

Out of the 30 registered patients, the majority belonged to the age group of 31–45 years (61.66%); female patients between 18 and 45 years were included for study. The majority of the participants were housewives, i.e., 41.67%. Dietary Habit-wise distribution shows that maximum patients were doing *Viruddha Ahara Sevana*, followed by patients having *Vishamashana Sevana*, which vitiate *Tridosha*, causes *Agnimandya*, which is a very important factor for the pathophysiology of hypothyroidism. Habit-wise distribution of patients shows that maximum was addicted to tea and coffee consumption (68.33%) as these products are widely used as formal supplements and welcome drinks in the present era. Nearly 100% of the patients had the habit of holding their natural urges (*Vegasandharana*). About 65% of the patients had *Krura Koshtha*. *Agni*-wise distribution shows that the maximum patients were found to have *Mandagni*, i.e., 70%. *Sharira Prakriti*-wise distribution shows that they were having *Vata-Kaphaja Prakriti* (75%) in major number. *Manasika Prakriti*-wise distribution shows that the maximum number of patients were having *Tamsik Prakriti* (55%), followed by *Rajasik Manas Prakriti*, i.e., 40%. *Sara* and *Satva*-wise distribution shows maximum patients were having *Avara Sara*, i.e., 53.33% and *Avara Satva*, i.e., 55%. The majority of patients (33.33%) had a tensive nature and 28.33% had a sentimental nature.

Mode of action of trial drugs: A combination of two drugs was given as treatment, namely, *Triphaladya Guggulu* and *Panchkol Phant*. The trial drug *Triphaladya Guggulu* is cited in *Yogaratnakara Gandamala Chikitsa* consists of *Guggulu* and *Madhu* in combination with *Trikatu*, *Triphala*, and *Kanchanara*.[8] *Guggulu* possesses digestive property to normalize excretory function, scraping of vitiated *Meda* with non-desirable *Dhatu* and *Vata*‑*Kapha* pacification properties. *Trikatu* is known to have digestive and *Vata*‑*Kapha* pacification properties. Digestive drugs prevent the formation of *Ama*, thereby preventing damage by keeping a balanced state of digestion and metabolism. *Triphala* has *Tridosha* pacification properties and supports healthy digestion and absorption. *Kanchanar* is described in *Kashaya Varga* or as *Chardana Gana*. It has *Kashya Rasa*, *Sheeta Veerya*, *Laghu*, and *Ruksha Guna* and act as *Deepana*, *Grahi*, *Medohara*, *Dhatvagnimandyatahara*, *Urdwajatru Vikaraharan* and *Doshaghnata- Tridoshahara*. In Ayurveda, *Kanchanar* is conventionally practiced in *Arbuda*, *Galaganda*, *Ashthila*, *Krimighana*, and *Kapha-Meda* dominant diseases and disorders. Madhu is one of the best *Yogvahi* Substances i.e., without changing its own properties, honey carries the effect of the drugs added to it. According to *Acharya Charak*, it has *Madhura- Kashya Rasa*, *Sheeta Veerya*, *Guru* and *Ruksha Guna*, *Doshaghnata- Vata Karak* and *Kapha-Pitta Nashak*, but *Sushruta* mentioned as *Tridosha Nashak* Along with *Madhura Rasa* with *Laghu*, *Ruksh*, and *Picchila Guna*.

Panchkol mentioned in *Bhavprakaash Samhita*[9] contains *Pippali*, *Pippalimula*, *Chavya*, *Chitraka* and *Shunti* mixing up in the form of fine powder in *Kola Parmana* (6 grams) each. It is *Tridoshgana*, *Ruchyam*, *Deepana*, *Pachana*, *Svaraharan*, *Medaharam*, *Shoolaghana*, *Gulmarti Nashanam* in nature. The treatment was given for 2 months, and the medicines given have shown promising results.

CONCLUSION

From the above study, it can be concluded that *Triphaladya Guggulu* along with *Panchkol phant* are effective in the management of hypothyroidism. So, there was a significant reduction in the signs and symptoms of the disease along with objective parameters. No side effects or any complications were seen. Formal behavioural modification programs may act as adjuvants or encourage the people to take responsibility for changing the lifestyle, which will determine the dietary habit combined with *yoga* that can prevent or treat hypothyroidism and nullify the complications of hypothyroidism. Thus, hypothyroidism, the metabolic disorder, can be treated effectively with the help of *Ayurvedic* principles.

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