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## Evaluating the Effect of Kapha Medohar Polyherbal Formulation in the Management of Hypothyroidism: A Pilot Study

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### Abstract

**Background:** Increased modernization, unhealthy lifestyles and faulty diet are the main factors contributing in disturbed metabolism of body and leads to various lifestyle related endocrine disorders. *Hypothyroidism* is a condition with hypometabolic clinical state resulting from inadequate production of thyroid hormone for prolonged period. About 42 million people in India is suffering from thyroid disorders. Certain thyroid disorders have detrimental effects on blood pressure, exacerbation of insulin resistance and atrial fibrillations. While understanding the aetiopathogenesis of hypothyroidism in Ayurvedic view, *Agni dushti*, *dhatwagni mandya janya vikruti*, *kapha vata dosha vrudhhi* & *pitta kshaya* due to Agni mandya are conditions suggestive of pathologies involved in hypothyroidism.

**Objective:** The present study was intended to assess the efficacy of kapha medohr polyherbal formulation in the clinical sign and symptoms and thyroid hormone level of patients suffering with Hypothyroidism.

**Materials and Methods:** Study was carried in outpatient department of Pt. khushilal Sharma Govt. Ayurvedic hospital Bhopal. Overall, 10 patients were included in the study fulfilling the diagnostic, inclusion and exclusion criteria. Newly diagnosed patients of hypothyroidism presenting with symptoms of weight gain, dry skin, constipation, lethargy, excessive sleep, hair loss and menstrual irregularities were selected for the study. To counteract all these conditions, kapha kaphamedohar polyherbal ghan vati comprising of (varuna, jalkumbhi, vidanga, kanchnar, pippali, marich, shunthi, amalki, haritaki, vibhitaki, sahijan) in dosage of 500 mg each vati was given twice daily before meal for duration of 60 days.

**Result:** After 2 months of treatment the patient shows significant response on reduction of serum TSH level. The mean score of S.TSH, before treatment was 7.98 and after treatment it was reduced to 4.49 with percentage relief of 43% which was extremely significant. Also there was significant improvement in almost all signs and symptoms with maximum relief in dryness, constipation and weight gain.

**Conclusion:** The present cases of hypothyroidism has been successfully treated with effective Ayurvedic treatment regimen. Herbal formulation showed statistically significant result without any complication.

**Keywords:** Hypothyroidism, Agnimandya, kapha medohar polyherbal formulation.

### Introduction

Hypothyroidism is the major endocrine disorder seen in general population. Endocrine system helps to regulate and maintain various body functions by synthesizing and releasing hormones. Thyroid gland produces 3 hormones thyroxine T<sub>4</sub>, Triiodothyronine T<sub>3</sub> & calcitonin. Hypothyroidism is a hypometabolic clinical state resulting from inadequate production of thyroid hormone for prolonged period. It is most common thyroid disorders in India, affecting one in ten adults<sup>1</sup>. They have potentially devastating health consequences that affect the population worldwide. TDs are frequently encountered and worsens the cases of atherosclerosis & diabetes mellitus. The most common cause of primary hypothyroidism in North America is Hashimotos Thyroiditis in which the gland is gradually destroyed due to autoimmune reaction resulting in hypothyroidism<sup>[2]</sup>. Treatment of

hyperthyroidism (over active thyroid gland), goiter & thyroid cancer using radioactive iodine to suppress thyroid function is the second leading cause<sup>[3]</sup>.

Clinical Manifestation shows generalized slowing of metabolic processes, Weight gain along with fatigue or lethargy, cold intolerance and high cholesterol, hair loss, hair becomes coarse & dry, skin becomes coarse, dry, hoarse voice, menorrhagia and secondary amenorrhoea.

Although, after mere knowledge of disorder pertaining the thyroid gland from view of modern system of medicines, we can't directly correlate in *Ayurveda* as a whole disease yet signs and symptoms which we approach in day-to-day clinical practice can be seen in *Ayurvedic* texts in different manners.

According to ayurvedic principles hypothyroidism is basically caused due to dysfunctioning of *Agni*. Hypofunctioning of *jatharagni*, which in turn affects *dhatwagni* eventually

responsible for pathological sequence & ultimately disease condition developed. Looking in to its *Doshika* dominance, *Kapha* associated *Pitta Dushti* with vitiation of *Vayu* due to *Margavarana* and predominantly *Annavaha*, *Rasavaha* and *Medovaha Srotodushti* can be considered as cause of the disease.<sup>(4)</sup> Keeping in consideration the *doshas*, *dhatu*, concept of *agni mandyata*, *sroto avarodha*, hypothyroidism can be well managed with ayurvedic principles like *ampachan*, *agni deepan*, *vatanuloman* & *kapha shaman* along with proper dietary management, advice of daily and seasonal regimen, detoxification procedures, medications (like *agnitundi vati*, *kanchnar guggulu*) & rejuvenation therapies. There are various evidences of ancient civilizations using herbal drugs in the treatment of diseases and for revitalising body system by ayurvedic formulations. In India, drugs of herbal origin have been used since ancient times in traditional systems of medicine such as Siddha and Ayurveda. Therefore present study has been planned with administration of *ghan vati* prepared from herbal drugs for effective management of hypothyroidism.

### Aim and Objectives

This pilot study provides an understanding to efficacy of *kapha medohar polyherbal* formulation in clinical signs and symptoms and thyroid hormone levels in the management of hypothyroidism according to Ayurvedic perspective.

**Material and Methods:** Literary review of hypothyroidism is collected from Ayurvedic samhita, journals, articles and modern texts.

**Source of Patient:** The patients suffering from symptoms of hypothyroidism attending the OPD of Pt. Khushilal Sharma Govt. Ayurvedic Hospital, Bhopal. Overall, 10 patients fulfilling the criteria for selection were included into the study irrespective of caste, religion etc. The clinical data along with the elaborated assessment of the condition were recorded in specially designed proforma. Among 10 patients, 9 completed the treatment, 1 patient did not complete the whole treatment due to unknown cause.

### Criteria for Selection

#### i). Diagnostic Criteria

##### a) Subjective Criteria

- Constipation
- Dry skin
- Excessive sleep
- Lethargy
- Hair Loss
- Weight gain
- Menorrhagia

**b) Objective Criteria:** Thyroid profile (Serum TSH, Serum T3, Serum T4)

#### ii). Inclusion Criteria

- Newly diagnosed case of hypothyroidism.
- Patients age should be between 18 to 60 years.
- Based on thyroid profile elevated level of serum TSH level or low level of serum T3 & T4. However, the cases of which T3 and T4 levels are within normal range and TSH level is high will also included.
- Patients those have given written consent to participate in the study.

#### iii). Exclusion Criteria

- All complicated cases of Hypothyroidism Goiter, myxoedema, severe mental illness,
- thyroid cancer etc. and associated with other endocrine disorders
- Patients having chronic systemic illness.
- Congenital hypothyroidism
- Pregnant women and Lactating Mother.
- Patients having undergone thyroid surgery

#### Assessment Criteria

The Improvement in the Clinical sign and symptoms will be assessed by adopting the following scale.

**Table 1:** Constipation

No constipation	0
Motion once in a day without complete evacuation	1
Motion once in two days	2
Motion once in more than two days with hard stool	3

**Table 2:** Dry skin

No dryness	0
Dryness after bath only	1
Dryness whole day but relieved by oil application	2
Dryness whole day and not relieved by oil application	3

**Table 3:** Excessive sleep

6 to 7 hrs/day	1
8 to 9 hrs/day	2
10 hrs/day	3
More than 10 hrs/day	4

**Table 4:** Lethargy

Doing work satisfactorily with proper vigour in time-	0
Doing work without desire, unsatisfactorily but in time-	1
Doing work without desire, unsatisfactorily, with lot of mental pressure and not in time	2
Not starting any work in his/her own responsibility, doing little work very slow	3

**Table 5:** Hair loss

Absent	0
Hair Fall on washing	2
Hair Fall on combing	3
Hair Fall on simple stretching	4

**Table 6:** Weight gain

BMI between 18.5 to 24.9	0
25 to 29.9	1
30 to 34.9	2
Above 35	3

#### Statistical Analysis

After completion of the treatment results were statistically analyzed in the terms of mean score, standard deviation (SD), standard error (SE), paired t test, and p value at various levels.

### Criteria for Overall Assessment

The total effect of the treatment on 9 patients was calculated by taking the mean of percentage of improvement. The final overall effect was graded as cured, marked improvement, moderate improvement, mild improvement, and no improvement.

**Table 7:** Criteria for overall assessment of the intervention

Percentage of Improvement	Effect of Therapy
< 25%	No improvement
25-49%	Mild improvement
50-74%	Moderate improvement
75-99%	Marked improvement
100%	cured

### Therapeutic Intervention

11 herbal drugs namely Varuna, Jalkumbhi, Vidanga, Pippali, Marich, Shunthi, Kanchnar, Aamalki, Haritaki, Vibhitaki and

Sahijan were taken in ratio of 2:2:1:1:1:1:1:1:1:1:1 by weight respectively & ghanvati is prepared by classical method

**Doses:** 2 ghanvati 250mg twice a day before meal

**Duration:** 60 days

**Table 8:** Ingredients of polyherbal ghan vati

S. No.	Name of Drug	Botanical Name	Part Used	Ratio
1.	Varuna	Crataeva nurvala	Twak	2 part
2.	Jalkumbhi	Pistia stratiotes	Panchang	2 part
3.	Vidanga	Embelia ribes	Phal	1 part
4.	Pippali	Piper longum	Phal	1 part
5.	Marich	Piper nigrum	Phal	1 part
6.	Shunthi	Zingiber officinale	Kand	1 part
7.	Kanchnar	Bauhinia variegata	Twak	1 part
8.	Aamalki	Emblica officinalis	Phal	1 part
9.	Haritaki	Terminalia chebula	Phal	1 part
10.	Vibhitaki	Terminalia bellirica	Phal	1 part
11.	Sahijan	Moringao leifera	Panchang	1 part

**Table 9:** Result

S. No.	Symptoms	BT Mean	AT Mean	M.D	S.D.	S.E.	% Relief	T value	P value	Result
1.	Constipation	1.89	0.2	1.67	0.441	0.236	89%	7.0711	0.0001	ES
2.	Dry skin	1.56	0.11	1.44	0.333	0.176	92%	8.2219	0.0001	ES
3.	Excessive sleep	2	0.889	1.111	0.9280	0.3093	55.5%	3.592	0.0071	VS
4.	Lethargy	2.33	0.67	1.67	0.5	0.236	71%	7.0711	0.0001	ES
5.	Hair Loss	1.89	0.44	1.44	0.527	0.176	76%	8.2219	0.0001	ES
6.	Weight gain	1.78	0.22	1.56	0.44	0.176	87%	8.8544	0.0001	ES

VS-Very significant, ES-Extremely Significant, S-Significant, NS-Not significant

The values of data were expressed as a percentage of relief and mean-standard error of the mean. The data were analysed by Student's 't' test for comparing before and after treatment obtained scores. The level of significance is expressed as  $P > 0.05$  as insignificant,  $P < 0.05$  and  $0.01$  as significant,  $P < 0.0001$  as highly significant.

**Table 10:** Effect of treatment on thyroid hormone level

S. No.	Mean BT	Mean AT	Diff.	S.D.	S.E.	% Relief	t value	P value	Result
S.TSH	7.98	4.5	3.48	1.264	0.436	43.6	7.98	0.0001	ES

### Interpretation

**Constipation:** The mean score of constipation in this study, before treatment was 1.89 and after treatment it was reduced to 0.2. So, the mean difference was 1.67, with percentage relief of 89% which was statistically extremely significant ( $P=0.0001$ ).

**Dry Skin:** The mean score of dry skin in this study, before treatment was 1.56 and after treatment it was reduced to 0.11. So, the mean difference was 1.44, with percentage relief of 92% which was statistically extremely significant ( $P=0.0001$ ).

**Excessive Sleep:** The mean score of excessive sleep in this study, before treatment was 2 and after treatment it was reduced to 0.889. So, the mean difference was 1.111, with percentage relief of 55.5% which was statistically very significant ( $P=0.0071$ ).

**Lethargy:** The mean score of lethargy in this study, before treatment was 2.33 and after treatment it was reduced to 0.67. So, the mean difference was 1.67, with percentage relief of 71% which was statistically extremely significant ( $P=0.0001$ ).

**Hair Loss:** The mean score of hair loss in this study, before treatment was 1.89 and after treatment it was reduced to 0.44. So, the mean difference was 1.44, with percentage relief of 76% which was extremely significant ( $P=0.0001$ ).

**Weight Gain:** The mean score of weight gain in this study, before treatment was 1.78 and after treatment it was reduced to 0.22. So, the mean difference was 1.56, with percentage relief of 87% which was extremely significant ( $P=0.0001$ ).

**S.TSH--** the mean score of s.tsh in this study, before treatment was 7.98 and after treatment it was reduced to 4.5. So, the mean difference was 3.48, with percentage relief of 43% which was extremely significant ( $P=0.0001$ ).

**Table 11:** Overall Assessment of the intervention

Effect of Therapy	No. of Patients	Percentage
Cured	00	00%
Marked improvement	02	22%
Moderate improvement	06	66%
Mild improvement	01	11%
No improvement	00	00%

Considering the overall effect of the intervention, 22% of the patients had marked improvement, 66% of the patients were noted to have moderate improvement, 11% of the patients were noted to have mild improvement and none of the patients showed complete remission & no one remained unimproved. Thus, the overall outcome of this study was very significant, indicating that the trial drugs as per reference of the Ayurveda text have an effective role in the treatment of Hypothyroidism.

## Discussion

Life's span, strength, health, lusture, immunity, energy, heat processes and vital breath all these depends on *jatharagni*. Due to various ill dietary habits and lifestyle modifications, the *Agnidushti* (Malfunctioning of fire) occurs and thus there is the formation of *Ama* (Undigested Food). Clinical presentation of hypothyroidism exhibits symptoms like fatigue, heaviness in the body, sleepiness, loss of appetite shows resemblance with *kapha avrut vata and sama dosha*. As per *Ayurveda* route cause of Hypothyroidism includes *Agni dushti*, *Dhatwagni mandya janya vikriti* <sup>(5)</sup> *vata kapha medovikrati*<sup>6</sup>, *kaphavrita vata* <sup>7</sup> and *kapha vata dosha vrudhhi & pitta kshaya* due to *Agnimandya*<sup>8</sup>, etc. To counteract all these conditions *Srotoshodhana*, *Agnidipan*, *pachan*, *vatanuloman* and *Kapha Shaman* are the main principles to be work out. Keeping in view of above mentioned conditions an effective *Ayurvedic* management comprising of polyherbal *ghan vati* have been used to manage the symptoms of hypothyroidism.

Individual mode of action and benefits of contents of herbal formulation:

**Mode of Action of Varuna:** *Varun Twak* is having *Laghu*, *Ruksha Guna*, *Ushna Virya*, *Katu Vipaka* and *Kapha- Vata-Medohar* property. In a recent study, the bark extract of *Varuna* (*crateva nurvala*) had shown to possess significant thyroid stimulant activity. It showed significant improvement in thyroid hormone levels and reduction in cholesterol levels proving its beneficial role in the treatment of hypothyroidism and associated hypercholesterolemia.<sup>9</sup>

**Mode of Action of Vidanga-** *Vidanga* has *Laghu*, *Ruksha*, *Tikshna*, *Ushna*, *Dipan* and *Vata Kapha Shamak* properties. *Vidanga* having *Kapha-Vata Shamaka*, *Katu*, *Ushna*, *Tikshana*, *Deepan* and *Vatanulomana* properties,<sup>[10]</sup> therefore it increase *Dhatvagni*, remove *Ama*, clears *Srotorodha*, subside *Avarana janya Vata* and thus relieves the symptoms.

**Mode of Action of Pippali:** *Pippali* possesses *Deepana*, *Pachana*, *Shothahara* qualities, it has *Ushna Veerya* and *Teekshna Guna*-<sup>[11]</sup> these properties of *pippali* are specifically directed to breakdown the *samprapti* of Hypothyroidism. *Pippali* have anti-hyperlipidemic, anti-obesity, and bio-enhancing properties due to presence of certain chemical constituents<sup>[12]</sup> which could have facilitated correcting the deranged metabolism of fat, carbohydrate, micronutrients etc. which is principally hampered in Hypothyroidism.

**Mode of Action of Marich:** *Maricha* is having *Kapha Vata Shamak* action on *dosa*, *vatashamak* due to *usna virya* and *kapha shaman* because of *usna virya*, *katu vipaka*, *katu ras*. with these properties it corrects *agnimandya* and thus reliving the symptoms of hypothyroidism.

**Mode of Action of Shunthi:** *Ushna Veerya* of *Shunthi* enhances the breakdown of fat at mitochondrial level, increases basal metabolic weight, oxygen consumption (Upadhaya et.al in 1979 at BHU has proved it). *Sunthi* undergoes *Madhur Vipaka* and thus has anabolic effect on the body. *Sunthi* helps in improving tissue development and nourishment by direct enrichment of the nutritional quality of the *Rasa Dhatu*.

**Mode of Action of Kanchnar:** *Kachnar* is another herb used in both enlargement of the thyroid as well as hypothyroidism. Having *Katu*, *Kashya Rasa* which makes the drugs to act as *Kapha shamaka*, *Pitta Vardhaka* and *Ama Dosha hara* drugs. These *Rasa* have tendency of reducing *Kapha* and *Meda dhatu*. *Katu rasa* removes the obstruction and thus correct the *Srotorodha*. *Kashya rasa* has *Lekhan Guna* that scraps out excessive *Kapha* and *Meda* from *Srotasa*.

**Mode of Action of Triphala:** Individual components of *Triphala* (*Amalki*, *Haritaki*, *Vibhitaki*) has natural antioxidants that can reverse thyroid damage and prevent adverse effects on health by optimizing thyroid function. *Triphala* helps in proper metabolism and digestion of food and also to cure symptoms like excessive heaviness, weight gain, and poor appetite. *Triphala* has *Tridosha* pacification properties and supports healthy digestion and absorption.

**Mode of Action of Sahijan:** *Shigru* is mentioned in *Guduchyadi varga*. It is *Katu (kshariya)*, *Tikta in rasa*, *Katu* in *Vipaka* and *Ushna in Veerya*. It possesses *Laghu*, *Ruksha* and *Tikshna guna*. He also mentioned that *Shigru* has *deepan*, *pachan & kaphavatahara* properties. It is recommended in *galganda*, *shoth*, *apachi*, *medorog*, *vidradhi*, *gulma* etc.

**Mode of Action of Jalkumbhi:** *Jalkumbhi bhasma* has *shothahara* properties. It has *Tikta*, *Madhura rasa & Laghu*, *Ruksha guna* and *tridosha shamaka* properties. So, due to *Tikta rasa* and *Laghu*, *Ruksha guna Jalakumbhi* act as *Ama Pachana* and *shamana* of aggravated *kapha*, hence increasing the *Dhatwagni*, removing *Ama lakshanas* of the body.

## Conclusion

*Hypothyroidism* is the most common form of thyroid disorders and commonly encountered problem in clinical practice. Hypothyroidism is basically a metabolic disorder with disturbed metabolism at cellular level. *Agni Dushti* (Malfunctioning of Digestive Fire), *Agnimandya* (Low Digestive Fire) is precursor factor of all the diseases resulting in *Ama* (Undigested food) formation. Attempt has been made to successfully counteract the pathogenesis, managing the symptoms and thyroid hormone level on the basis of *doshik combination pattern*, *dhatwagni mandya* and *concept of kaphavrita vata*. Thus multifactorial and holistic approach is required in effectively managing the condition of hypothyroidism i.e. drug, diet and regular yogic exercises all together helps in improving thyroid functions in hypothyroidism.

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