

A clinical study to evaluate the role of *Triphaladya Guggulu* along with *Punarnavadi Kashaya* in the management of hypothyroidism

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Abstract

Context: Hypothyroidism is one of the most common thyroid disorders in India, affecting one in ten adults. Although the diagnosis and treatment of hypothyroidism are often considered simple, there are large number of people with this condition who are suboptimally treated. Due to wide spectrum of the disease and high prevalence in the society, the current issue was opted for study and its management by means of Ayurvedic principles. **Materials and Methods:** Fifteen eligible hypothyroid patients with serum thyroid-stimulating hormone $>4.5 \mu\text{IU/ml}$ and serum T_3 and T_4 lower than their respective normal range were selected and treated with *Triphaladya Guggulu* pills and *Punarnavadi Kashayam* (decoction) for 45 days. Patients were advised to discontinue any medicine they might be taking for the management of hypothyroidism to assess the unbiased effect of therapies. **Results:** Significant improvement was observed on subjective parameters, but the results on objective parameters were statistically insignificant ($P > 0.05$). Of the 15 enrolled patients, excellent improvement was observed in 33.33% of the patients, while marked improvement was reported by 53.33% of the patients, moderate improvement was found in 6.66% of the patients and same number of patients, that is, 6.66% showed mild improvement. Moreover, few interesting observations were noted 4 months after completion of the trial. Out of 15 patients registered, 86.66% had positive drug history for levothyroxine. After clinical trial, 6.66% of the patients continued their previous dosage of levothyroxine, while 80% of the patients had withdrawn their hormone replacement therapy. **Conclusion:** *Triphaladya Guggulu* and *Punarnavadi* decoction are effective in the management of hypothyroidism.

Keywords: Hypothyroidism, *Punarnavadi* decoction, *Triphaladya Guggulu*

Introduction

The incidence of thyroid disorders in India is high, with hypothyroidism being a condition that is not adequately controlled in the country at present. Lack of thyroid hormone or resistance of the body tissue to thyroid hormone with respect to metabolic demand results in disorder called hypothyroidism. Thyroid hormone is required for the normal functioning of each and every tissue of the body. Hence, its deficiency manifests as multisystem involvement. It is estimated that about 42 million people suffer from thyroid disorders in India, of which hypothyroidism is most common with a prevalence of 5.4%.^[1] The modern system of medicine is still exploring medicine for better and more effective management of hypothyroidism. Synthetic thyroid hormone derivatives may bring the value of thyroid-stimulating hormone (TSH) and T_4 to normal range, but the increased dosage and continuous medicine make the

patient drug dependent till the end of the life. Even after years of treatment, it is associated with failure to provide relief in clinical manifestations. Moreover, excessive thyroid hormone replacement carries the potential for serious long-term metabolic complications (e.g., accelerated osteoporosis).^[2]

The major function of the thyroid gland is to act as a spark for the maintenance of oxidative metabolism in most tissues. In Ayurveda parlance, this is attributed as the function of *Agni* (system related to metabolism). As far as the management of hypothyroidism through Ayurveda is concerned, hormonal replacement is not possible through drugs. However, one can

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interpret the pathogenesis of hypothyroidism in the context of Ayurveda, in which role of *Agni* is foremost and through its management, wholesome normal activity of the thyroid gland may be achieved. The objective of treatment should be to address the problem at its root by regulating the immune system and decreasing inflammation. *Srotoshodhana* (cleansing of the macro and microchannels), *Agnideepana* (stimulation of the digestion and metabolism), *Pachana* (digestion) and *Vatanulomana* (proper regulation of excretory system) are the main principles of treatment.

The trial drug *Punarnavadi Kashayam*^[3] is mentioned in *Chakradatta* for the management of *Shotha (odema)*, which is one of the common manifestations of hypothyroidism. It contains *Punarnava*, *Devadaru* and *Shunthi* along with *Guggulu*. *Triphladya Guggulu*^[4] is cited in *Yogaratanakara* for the management of *Gandamala*. It contains *Guggulu* in combination with *Trikatu*, *Triphala* and *Kanchanara*. The drug possesses *Deepana-Pachana Dravya* along with *Kanchanara*, which is widely being practiced for the management of hypothyroidism. Thus, keeping in mind the possible effects of trial drugs in normalizing the impaired *Agni*, they were selected to evaluate their efficacy in the management of hypothyroidism.

Materials and Methods

Selection of patients

A total of 15 patients suffering from hypothyroidism were selected from outdoor patient department and indoor patient department of Panchakarma, IPGT & RA, Jamnagar, irrespective of their sex, religion, caste, occupation etc.

Ethical clearance was obtained from the Institutional ethics committee vide PGT/7-A/Ethics/2015-2016/1490/2.42 dated August 25, 2015. This study is registered in Clinical Trial Registry of India with registration no. CTRI/2016/10/007378. Informed written consent in language suitable to the patients was obtained from all enrolled participants.

Inclusion criteria

- Diagnosed cases of hypothyroidism on the basis of serum TSH, T₃ and T₄ levels.
 - Patient's serum TSH level >4.5 µIU/ml^[5]
 - Total serum T₄ level less than normal value (total serum T₄ = 4.5–12.5 µg/dl)
 - Total serum T₃ level less than normal value (total serum T₃ = 80–220 ng/dl).
- Patients having clinical features of hypothyroidism:
 - Puffiness of the face and eyelids
 - Peripheral edema
 - Dry coarse skin
 - Breathlessness
 - Constipation
 - Weakness
 - Lethargy
 - Fatigue
 - Muscle ache

- Menstrual abnormality
- Hair loss
- Age 20–60 years.

Exclusion criteria

Patients with ischemic heart disease, uncontrolled hypertension, myocardial infarction, cerebrovascular event, cardiac arrhythmias, pregnancy and active malignant disease were excluded from the study.

Laboratory investigations

- Routine hematological (complete blood count and erythrocyte sedimentation rate) investigation.
- Thyroid profile (serum T₃, serum T₄, serum TSH)
- 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.

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 1 week before including the patient in the clinical trial.

All the patients were advised to take meal only upon hungry, green gram predominant diet, to avoid full stomach diet and to refrain from dairy products or heavy to digest food articles. Patients were strictly advised to abstain from day sleep during the trial period.

Drugs and dosage

- *Triphladya Guggulu* 2 Vati twice daily (each Vati weighing 500 mg) with lukewarm water after meal
- *Punarnavadi* decoction 30 ml twice a day before meal.

The trial drugs were procured from Pharmacy, Gujarat Ayurved University. Ingredients of the same are mentioned in Tables 1 and 2.

Preparation method of trial drugs

Triphladya Guggulu

T. Guggulu was prepared by dissolving *Triphala* purified *Guggulu* in *Kanchanara* bark decoction until it attained a

Table 1: Ingredients of *Triphaladya Guggulu*

Drug	Latin name	Part used	Quantity
<i>Shunthi</i>	<i>Zingiber officinale</i> Roxb.	Rhizome	1 part
<i>Pippali</i>	<i>Piper longum</i> Linn.	Fruit	1 part
<i>Maricha</i>	<i>Piper nigrum</i> Linn.	Fruit	1 part
<i>Amalaki</i>	<i>Emblica officinalis</i> Gaertn.	Fruit	1 part
<i>Haritaki</i>	<i>Terminalia chebula</i> Retz.	Fruit	
<i>Bibhitaki</i>	<i>Terminalia bellerica</i> Roxb.	Fruit	
<i>Kanchanara</i>	<i>Bauhinia variegata</i> (L.) Benth.	Bark	6 parts
<i>Guggulu</i>	<i>Commiphora mukul</i> (Hook. ex Stocks) Engl.	Resin	10 parts
<i>Madhu</i>	<i>Honey</i>	-	QS

Table 2: Ingredients of *Punarnavadi Kashaya*

Drug	Latin name	Part used	Quantity
<i>Punarnava</i>	<i>Boerhavia diffusa</i> Linn.	Root	15 kg
<i>Devdaru</i>	<i>Cedrus deodara</i> (Roxb.) Loud.	Stem	15 kg
<i>Shunthi</i>	<i>Zingiber officinale</i> Roxb.	Rhizome	15 kg
<i>Guggulu</i>	<i>Commiphora mukul</i> (Hook. ex Stocks) Engl.	Resin	500 gm

sticky consistency, followed by addition of powders of *Trikatu* and *Triphala* along with quantity sufficient honey for making pills of 500 mg size.

Preparation of *Punarnavadi Kashayam*

Patients were advised to boil 15 g of coarse powder of *Punarnavadi Yavakuta* in eight parts of water and reduce it to one-fourth over mild heat and to consume it empty stomach twice daily.

The trial drugs were administered for 45 days.

Follow-up study

After completion of the therapy, patients were followed for 1 month.

Criteria for assessment

- 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 [Table 3]^[5]
- Thyroid profile (Serum TSH, T₃ and T₄).

Statistical analysis

The data obtained in the study were subjected to statistical analysis to evaluate the significance of curative effect of therapies.

Subjective criteria

Percentage of improvement in each parameter was calculated. Wilcoxon's signed-rank test was applied to the data to analyze the effect of therapy on subjective parameters.

Objective criteria

Obtained data of objective parameters were subjected to student's paired *t*-test to analyze the effect of therapy on objective parameters.

The results were interpreted at $P < 0.05$, $P < 0.01$ and $P < 0.001$ significance levels.

Observations

Out of the 15 registered patients, maximum patients belonged to age group of 31–40 years (60%) and majority of the participants were female (93.34%). History of hypertension was reported in 93.34% of the patients. Family history of hypothyroidism was positive in 40% of the patients. Chronicity more than 5 years was reported in 40% of the patients. *Samashana* (taking wholesome and unwholesome food together) and *Adhyashana* (eating in spite of indigestion) were practiced by 80% and 53.34% of the patients, respectively. *Lavana Rasa* (salty), *Madhura*

Table 3: a-I: Grading criteria

Symptoms	Score	
a. Puffiness		
Absent	0	
Occasional	1	
Daily periorbital edema/puffiness in the morning, relieved in later part of day	2	
Persistent	3	
b. Edema		
Absent	0	
Edema over lower/upper extremities	1	
Edema over both extremities	2	
Edema all over the body	3	
c. Dry and coarse skin		
No dryness	0	
Dryness after bath only	1	
Dryness all over body but relieved by oil application	2	
Dryness not even relieved by oil application	3	
d. Breathlessness		
Absent	0	
Occasionally, only after strenuous workout	1	
Even on climbing upstairs, but relieved by rest	2	
Felt in routine work - bathing, changing clothes	3	
e. Constipation		
Frequency	Consistency	Straining
Once a day-0	<i>Shithila</i> -0	No-0
Once in two days-1	<i>Madhyama</i> -1	Occasionally, bearable-1
Once in three days-2	<i>Kathina</i> -2	Frequently, severe-2
Once in more than three days-3	<i>Granthil</i> -3	
f. Weakness		
Able to exercise without difficulty		0
Able to do mild exercise		1
Able to do only mild work		2
Able to do mild work with difficulty		3
Not able to do even mild work		4
Unable to do even day-to-day routine work		5
g. Lethargy		
Doing work satisfactorily with proper vigor 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
Does not have any initiation and not want to work even after pressure		4
h. Fatigue		
Normal		0
Patient likes to stand in comparison to walk		1
Patient likes sit in comparison to stand		2
Patient likes to lie down in comparison with sitting		3
Patient likes to sleep in comparison with lying down		4
i. Muscle ache		
No		0
Relieved by rest		1

Contd...

Table 3: Contd...

Symptoms	Score
i. Muscle ache	
Not relieved by rest but relieved by Ext application	2
Requires external application and internal medication	3
Present consistently	4
j. Duration of menstrual blood	
4-7 days	0
3 days	1
2 days	2
1 day	3
k. Interval between two cycles	
25-29 days	0
35-39 days	1
40-45 days	2
>45 days	3
l. Hair fall	
Absent	0
Hair fall on washing	1
Hair fall on combing	2
Hair fall on simple stretching	3

Rasa (sweet), *Katu Rasa* (pungent taste) and *Amla Rasa* (sour) predominant diet were reported being consumed by 100%, 93.34%, 93.34% and 66.67% of the patients, respectively. Nearly 100% of the patients had the habit of holding their natural urges (*Vegasandharana*). About 86.67% of the patients reported *Avyayama* (lack of exercise). *Divaswapna* (day sleep) was practiced by 73.34% of the patients. *Atichintana* (over worry) was found in 73.34% of the patients. *Mandagni* (weak digestive system) was observed in 60% of the patients. About 66.67% of the patients had *Krura Koshtha* (costive bowel). Symptoms of vitiation of *Rasavaha* and *Medovaha Srotasa* were observed in 100% of the patients followed by *Annavaha Srotodushiti* in 93.33% of the cases.

Results

Effect of therapy on presenting complaints of hypothyroidism

The results were significant in almost all the signs and symptoms of hypothyroidism. Highly significant improvement ($P < 0.001$) was observed in weakness, fatigue and muscle ache and the results were statistically significant ($P < 0.01$) on all the other complaints such as puffiness over the face and eyelids, peripheral edema and dry coarse skin [Table 4].

Effect of therapy on weight and body mass index

There was a significant decrease ($P < 0.01$) in weight and body mass index by 3.14% and 3.20%, respectively [Table 5].

Effect of therapy on thyroid profile

Serum TSH was insignificantly elevated ($P > 0.05$) by 40.66%, serum T_3 was insignificantly decreased ($P > 0.05$) by 6.78%, and an increase of 7.95% in serum T_4 was observed which was statistically insignificant [Table 6].

Effect of therapy on hematological parameters and lipid profile

There was statistically insignificant change ($P > 0.05$) in all the hematological parameters and lipid profile.

Overall effect of therapy

Excellent improvement was found in 33.33% of the patients 53.33% of the patients showed marked improvement, 6.66% of the patients showed moderate improvement and same percentage that is 6.66% of the patients showed mild improvement. None of the patients remained unchanged [Table 7].

Discussion

In most cases of hypothyroidism, a specific cause is not apparent. It is believed that hypothyroidism is usually secondary to an autoimmune reaction.^[6] In autoimmune disorders, the immune system cells do not recognize the cell as “self” and mount an immune response against them. This self-attack by the immune system increases inflammation and inflammation has a profound effect on all aspects of thyroid metabolism and physiology. Pro-inflammatory cytokines can inhibit type 2 5'-deiodinase enzyme activity which is required for the conversion of T_4 to T_3 .^[7] Inflammation causes elevated cortisol levels, leading to a decrease in TSH and lowered thyroid hormone production. Cortisol also inhibits the conversion of T_4 to active T_3 and increases the conversion of T_4 to reverse T_3 .^[8] Thyroid hormones stimulate diverse metabolic activities in most tissues, leading to an increase in basal metabolic rate. By way of analogy, the action of thyroid hormones is akin to *Agni*. The cause of disease, that is, impaired metabolism can be compared with *Agnimandya*.

Discussion on effect of therapy on thyroid profile

Out of 15 patients in the present trial, 10 patients had encouraging results in thyroid profile, not much change in thyroid profile was observed in 2 patients but the result worsened in 3 patients. On retrospective analysis, it was observed that patients whose thyroid profile had worsened during the trial had *Vata-Kapha Prakriti*, which can make the disease condition difficult to treat, due to the *Vata-Kapha* predominance in disease. Chronicity in those cases was reported to be more than 5 years. All of them had positive history for intake of levothyroxine. Chronicity and past treatment history can also be considered as one of the factors for negative results. Stress was a common factor in all these patients. One of these patients was a case of hypothyroidism caused after the treatment for Grave's disease and in patients who develop hypothyroidism after the treatment of Graves' disease, there is often an underlying autonomous function, necessitating lower replacement dose. This might be the reason why thyroid function worsened in this patient. The half-life elimination of thyroxine (T_4) in hypothyroid patients is 9–10 days.^[9] Half-life (abbreviated $t_{1/2}$) is the time required for a quantity to reduce to half its initial value, but the washout period in the present trial was 7 days, this reflects

Table 4: Effect of therapy on chief complaints using Wilcoxon's signed-rank test

Chief complaint	n	Mean values		Diff	Percentage difference	W	P	Significance
		BT	AT					
Puffiness of the face and eyelids	12	1.733	0.467	1.267	73.11↓	-64.000	0.009	S
Peripheral edema	11	1.533	0.267	1.267	82.48↓	-55.000	0.002	S
Dry coarse skin	11	1.533	0.667	0.867	56.55↓	-48.000	0.010	S
Breathlessness	9	1.133	0.400	0.733	64.69↓	-36.000	0.008	S
Constipation	11	1.200	0.400	0.800	66.67↓	-55.000	0.002	S
Weakness	12	1.733	0.400	1.333	76.91↓	-78.000	<0.001	HS
Lethargy	12	1.333	0.400	0.933	69.99↓	-55.000	0.002	S
Fatigue	11	1.600	0.200	1.400	87.5↓	-66.000	<0.001	HS
Muscle ache	14	1.800	0.400	1.400	77.78↓	-91.000	<0.001	HS
Duration of menstrual blood	4	0.500	0.250	0.250	50↓	-3.000	0.500	IS
Interval between two cycles	2	0.500	0.250	0.250	50↓	-3.000	0.500	IS
Hair loss	9	1.429	0.714	0.714	50↓	-28.000	0.016	S

n: Number of patients, BT: Before treatment, AT: After treatment, Diff: Difference between mean values before and after treatment, ↓: Decrease, S: Significant ($P<0.01$), HS: Highly significant ($P<0.001$), IS: Insignificant ($P>0.05$)

Table 5: Effect of therapy on weight and body mass index

Parameter	n	BT	AT	Diff	Percentage	Paired t-test				Significance
						SD	SE	t	P	
Weight	15	75.367	73.000	2.367	3.14↓	2.567	0.663	3.571	0.003	S
BMI	15	30.353	29.380	0.973	3.20↓	1.031	0.266	3.655	0.003	S

n: Number of patients, BT: Before treatment, AT: After treatment, Diff: Difference between BT and AT, values, ↓: Decrease, SD: Standard deviation, SE: Standard error, S: Significant ($P<0.01$)

Table 6: Effect of therapy on thyroid profile

Parameter	n	BT	AT	Diff	Percentage	Paired t-test				Significance
						SD	SE	T	P	
Serum TSH (mIU/L)	15	28.073	39.490	-11.417	40.66↑	53.465	13.805	-0.827	0.422	IS
Serum T ₃ (nmol/L)	15	1.021	0.951	0.0693	6.78↓	0.307	0.0793	0.874	0.397	IS
Serum T ₄ (ng/dl)	15	4.787	5.168	-0.381	7.95↑	1.972	0.509	-0.747	0.467	IS

n: Number of patients, BT: Before treatment, AT: After treatment, Diff: Difference between BT and AT values, ↑: Increase, ↓: Decrease, SD: Standard deviation, SE: Standard error, IS: Insignificant ($P>0.05$), TSH: Thyroid-stimulating hormone

Table 7: Overall effect of therapy

Effect of therapy	Number of patients (%)
Excellent response (>75%≤100%)	5 (33.33)
Marked positive response (>50%≤75%)	8 (53.33)
Moderate positive response (>25%≤50%)	1 (6.66)
Mild positive response (≤25%)	1 (6.66)
No change (0%)	0 (0)

that before treatment thyroid profile was under the influence of levothyroxine, whereas after treatment, the change in thyroid profile was solely under the influence of trial interventions.

Recovery of the hypothalamic–pituitary axis usually requires 8 weeks at which time the TSH and free T₄ levels can be measured,^[10] that is, TSH responses are gradual and should be measured about 2 months after instituting treatment.^[11]

However, the duration of the trial was limited to 6 weeks. Despite the short duration of the clinical trial, positive changes were observed in thyroid profile in 10 of 15 patients.

Thus, from the above observations, it can be inferred that both the trial drugs were helpful in normalizing the thyroid function, but better results could have been possible if the duration of trial was longer.

Mode of action of trial drugs

In hypothyroidism, etiological factors mainly vitiate *Tridosha* (*Kapha* predominance associated *Pitta* vitiation and *Margavaranajanya* [hindrance of function] leading to provoking of *Vata*). This *Tridosha* vitiation invites derangement of *Jatharagni* (digestive system), ultimately leading to the derangement of *Dhatvagni* (metabolic system) and subsequent appearance of *Ama*. This *Ama* blocks the channels in the body (*Srotorodha*), thereby afflicting the

contents of channels causing vitiation of *Srotasa* as well as *Dhatu* to which these *Srotas* deliver.

The trial drug *Triphaladya Guggulu* is cited in *Yogaratanakara Gandamala Chikitsa* consists of *Guggulu* in combination with *Trikatu*, *Triphala* and *Kanchanara*. *Punarnava 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 balanced state of digestion and metabolism. *Triphala* has *Tridosha* pacification properties and supports healthy digestion and absorption.

Punarnavadi decoction mentioned in *Chakradatta Shotha Chikitsa* contains *Punarnava*, *Devadaru* and *Shunthi* along with *Guggulu* as an adjuvants. The roots of *Punarnava* are claimed to possess diuretic and laxative^[12] properties and thus might have been functional in alleviating swelling, the most common presenting complaint. *Devadaru* possesses anti-inflammatory, immune-modulatory and diuretic properties.^[13] Vitamin C is an active component of *Devadaru*.^[13] Studies have shown that natural antioxidant therapy such as Vitamin C can reverse thyroid damage and prevent adverse effects to health by optimizing thyroid function.^[14] Moreover, *Devadaru* has *Lekhana* action. These properties of *Devadaru* might have helped in reducing weight.^[13] *Shunthi* owns digestive, pain-alleviating and *Vata-Kapha* pacification properties, preventing the formation of *Ama*. Preventing the formation of *Ama* can correct the pathogenesis at the beginning itself.

Few observations noted after the trial

Out of 15 registered patients, 86.66% had positive drug history for consumption of levothyroxine. After clinical trial, 6.66% of the patients continued their previous dosage of levothyroxine, while 80% of the patients had withdrawn their hormone replacement therapy. Not all the 80% of the patients who had withdrawn levothyroxine could restore normal thyroid profile, but they were quite satisfied with Ayurvedic management and were not willing to resume previously on-going synthetic thyroxin. These observations were noted 4 months after the completion of the clinical trial. An additional observation was that on long-term follow-up, thyroid profile showed a trend toward normalcy even in the cases that could not restore normal thyroid profile during the trial.

Conclusion

Although any disease condition is not described in Ayurveda which is similar to hypothyroidism, it is found to possess a strong correlation with *Agnimandya* and *Ama*. The trial drugs

showed highly significant results on subjective parameters. Vitiation of *Dhatvagni* once created cannot be corrected easily; hence, *Shamana* therapy should be administered for sufficient time to cure *Ama* at *Dhatu* level. From the clinical trial, it can be concluded that *Triphaladya Guggulu* and *Punarnavadi* decoction are effective in the management of hypothyroidism.

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Conflicts of interest

There are no conflicts of interest.

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