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Effect of *Ayurveda* formulations in Primary Hypothyroidism with respect to *prakriti* - A multi-center clinical study

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Abstract

Primary hypothyroidism is defined as low levels of blood thyroid hormone due to destruction of the thyroid gland. Based on the signs and symptoms in Ayurvedic classics, Hypothyroidism can be described as *kapha-medo vridhi* and *dhātvāgnimāndhya* and considered as a condition called *galaganda.* Ayurveda stresses the importance of *prakriti* as a prognostic factor in the management of diseases. With due consideration, this study is intended to evaluate the effect of three commonly used indigenous formulations viz*., Hamsapathyadikashaya, Kanchanaraguggulu* and *Bhallatakalehya* in primary hypothyroidism when administered with respect to *dehaprakriti* of the individuals.

Objectives

1.To study the effect of *Hamsapathyadi kashaya* and *Bhallatakalehya* in *kapha* dominant *prakriti* with Primary hypothyroidism.

2.To study the effect of *Hamsapathyadi kashaya* and *Kanchanaraguggulu* in other *prakriti* (except *kapha* dominant) with Primary hypothyroidism.

Methodology

Study design - Two groups, Pre-post interventional

Study Setting - Govt. Ayurveda College Hospital, Tripunithura and VPSV Ayurveda College Hospital, Kottakkal.

102 patients with Primary Hypothyroidism were selected according to inclusion and exclusion criteria and subjected to *prakriti* assessment and grouped as A (*kapha* dominant) and B (vata & pitta dominant). Forty patients assigned to Group A were given *Ballathakalehya* and *Hamsapathyadi kashaya* and sixty-two participants in Group B were given *Kanchanara guggulu* and *Hamsapathyadi kashaya* for a duration of 60 days and follow up were done for corresponding 4 months. The parameters TFT (objective), Zulewski's clinical score and QOL with Nottingham Health Profile (subjective) were observed and assessed on 0^{th}, 60^{th} and 180^{th} days.

Results: The observed values were statistically analyzed by Paired t test. The TSH values of Group A shows statistical significance on 0^{th} day Vs 60^{th} day and 0^{th} day Vs 180^{th} day. TSH values of Group B shows statistical significance on 0^{th} day Vs 180^{th} day. T_3 and T_4 levels showed no significant difference in any of the group. The Zulewski's score and Quality of life assessment showed highly significant results in both Group A and Group B in all paired analysis.

Conclusion: When provided while taking the patient's *prakriti* into consideration, *Hamsapathyadi kashaya*, taken in combination with *Bhallataka Lehya* or *Kanchanaraguggulu*, is beneficial in lowering TSH levels, Zulewski's score and thus improving the Quality of life of patients with Primary Hypothyroidism.

Introduction

Hypothyroidism refers to the common pathological condition of thyroid hormone deficiency. If untreated, it can lead to serious adverse health effects. Because of the large variation in clinical presentation and general absence of symptom specificity, the diagnosis of hypothyroidism is predominantly biochemical. Overt or Clinical Primary hypothyroidism is said to be having the Thyroid Stimulating Hormone (TSH) concentrations higher and free thyroid hormones (T3/T4) concentrations less than the reference range. Mild or sub clinical hypothyroidism is characterized by TSH concentration exceeding the reference range whereas the free thyroxine concentrations remain within normal range. The reference ranges of these hormones are important because these are generally used as a threshold for treatment. Primary hypothyroidism usually presents with symptoms like Excessive tiredness, constipation, weight gain, puffy face, dry skin, hoarseness of voice, muscle aches, tenderness and stiffness, more sensitivity to cold etc. Thyroid hormone replacement with levothyroxine is the standard treatment for patients with hypothyroidism. However, a substantial portion of patients treated with levothyroxine have persistent complaints despite reaching the biochemical therapy especially in maintaining a good quality of life[1] This opens scope for Ayurvedic formulations in the treatment of Primary Hypothyroidism. Besides disease subsidence it has been seen that Ayurvedic medicines do play a vital role in maintaining the quality of life of the diseased.

Even though there is no direct description of Hypothyroidism in Ayurveda literature, the signs and symptoms presented in Hypothyroidism can be categorized under *Vata-Kapha-Medo vikriti* and *Dhatvagnimandya*. Most of the Ayurvedic physicians adopt the treatment principles stated in *Galaganda* [2]while treating Hypothyroidism. Tracing the pathogenesis of *galaganda*,it can been seen than the etiological factors that contribute are predominantly kapha-vata prakopa hetus which causes for *dhatvagnimandya* which is followed by *rasa dhathu dushti* followed in sequence by *mamsa- medo dushti* resulting in *Galaganda*. Even though the features of *Galaganda* simulates different types of goiters the references of *dushti lakshanas* of the *kapha vata doshas* and *rasa medo dhatus* simulates the symptoms of Hypothyroidism. So the medicines which act on these *dosha -dhatus* giving prior importance to *dhatvagnimandya* would definitely give result in the treatment of Hypothyroidism. So obviously the treatment protocol should include formulations which primarily *agni deepana pachana and kapha –medo hara properties*. Studies have been conducted on the effect of different Ayurvedic formulations in treating Hypothyroidism. A combination of *Hamsapathyadi Kashaya* [3]with *Kanchanara guggulu* [4]and *Bhallathaka yoga*[5] are being effectively used by many Ayurvedic physicians in their routine clinical practice. All the three of the above mentioned formulations comprises of drugs which are *deepana pachana* and *kapha medo hara*.

One among the prime criteria of medicine prescription in Ayurveda is Prakriti. As far as an endocrine disorder like Hypothyroidism is considered, *prakriti* can act as a vital component in selecting the medical intervention to tackle the disease. This can make the treatment more effective and subjective. The formulation *Hamsapathyadi kashaya* has a direct reference in the context of *Galaganda*. It has been widely used by Ayurvedic physicians irrespective of the *prakriti o*f the patient. So in this study too, *Hamsapathyadi Kashaya* is given patients in both groups irrespective of *prakriti* of the patients. When it comes to patients with *kapha* dominant *prakriti*,the choice of drug should be bit intense since the disease is also with *kapha* dominance. Hence *Bhallataka* is the drug of choice in such patients. *Kanchanara guggulu* acts effectively in *kapha dosha* with due consideration *of vata and pitta dosha*. Hence *Kanchanara guggulu* is given in patients of Hypothyroidism with *prakriti* other than *kapha* dominant. Thusthe present study is aimed to understand the effect of Ayurvedic intervention in Primary Hypothyroidism with reference to the medicine combinations of *Hamsapathyadi kashaya*either with *Kanchanara guggulu or Bhallataka lehya,* selected according to the *prakriti* of the patients with Primary Hypothyroidism.

AIMS AND OBJECTIVES

- To study the effect of *Hamsapathyadikashaya and Bhallatakalehya* in *kapha* dominant *prakriti* with Primary hypothyroidism.
- To study the effect of *Hamsapathyadi kashaya and Kanchanaraguggulu* in other *prakriti* (except *kapha* dominant) with Primary hypothyroidism.

METHODOLOGY

Study Design: Two groups Pre-post Interventional Design

Study Setting: This multi center clinical study was conducted at two Ayurveda medical Colleges in Keralaviz.,Govt. Ayurveda College, Tripunithura, and V.P.S.V Ayurveda College, Kottakkal, Malappuram.

Period Of Study: July 2019 to February 2022

Sample Size: The estimated total sample size was 120, 60 participants in each group (30 in each group at both centres).But affected by the Covid-19 pandemic, total participants screened and selected for the study was 118 including both centres, out of which 102 completed the study which included 42 from group A and 60 from group B.

Materials: *Hamsapathyadi kashaya, Bhallataka lehya*, *Kanchanaraguggulu tablets* were manufactured as single batch at Oushadhi Pharmaceutical Corporation, Kerala Ltd, Thrissur as per the reference texts.

Ethical Consideration: Institutional Ethics Committee Approval was obtained with

a) 37-08/SL-PJ/KUHS/IEC/2019 dated 11/04/2019 (Centre-1,GAVC,tripunithura)

a) IEC/CI/36/2019 dated 06/05/2019. (Centre-2,VPSV Ayurveda college, Kottakal)

Diagnostic Criteria:

1. Serum TSH levels between 4-20 mIU/L
2. A score of more than 5 in Zulewski's Clinical Score for Hypothyroidism[6]

Inclusion Criteria:

1. Age:18 - 60 years
2. Participants will be selected irrespective of *prakriti,* gender, caste, religion and economic status.
3. Participants who are non-sensitive to *Guggulu* and *Bhallataka.*
4. Participants who are competent and willing to provide written informed consent.

Table No.1

Formulations	Key Ingredients	Action and Indications
Hamsapathyadi kashaya,	*Hamsapadi(Adiantumlunulatum)* *Amrita(Tinosporacordifolia)* *Nimba(Azadirachta indica)* *Pippali(Piperlongum)* *Vasha(Adathoda vasica)*	*Galaganda*(goiter) *Gandamala*(nodules of neck)
Bhallataka lehya,	*Bhallataka(Semicarpus Anacardium)* *Tila(Sesamumindicum)* *pathya (Terminalia chebula)* *Kanchanara(Bauhiniavariegate) Shunti (Zingiberofficinale),* *Maricha(Piper nigrum),* *Pippali(Piper longum),*	*Vahnikara,* *Pachana,* *Kaphavatahara*
Kanchanaraguggulu	*Haritaki(Terminaliachebula),* *Vibhitaki(Terminaliabellerica)* *Amalaki(Emblica officinalis),* *Varuna(Crataevanurvala)* *Ela(Elettaria caradamomum)* *Twak(Cinnamomum zeylanicum)* *Patra(Cinnamomum tamala)* *Guggulu(Commiphora mukul)*	*Galaganda*(goiter) *Apache*(nodules of neck) *Arbuda*(tumours) *Granthi*(extra growths) *Vrana*(wounds) *Kushta(*skin diseases*)* *Bagandara*(fistula)

Exclusion Criteria:

1. Uncontrolled diabetes mellitus, uncontrolled hypertension.
2. Pregnant and lactating women.
3. Patient undergoing any known hormonal therapy.
4. Participants with evidence of malignancy.
5. Clinical evidence of cardiac diseases.
6. Participants taking medications for depression.
7. Secondary causes of hypothyroidism.

Intervention:

Selected Participants were grouped based on TNMC *prakriti* analysis Questionnaire [7]

Group A –Participants of *Kapha* dominant *prakriti*

- *Bhallathakalehya* (2.5 g twice daily for a period of 60 days)
- *Hamsapathyadi kashaya* (15ml+60ml luke warmwater,45 minutes before food twice daily for 60 days)

Group B - Participants of other *prakriti* except *Kapha* dominant

- *Kanchanaraguggulu(500gm)* (2-0-2 tablets ,after food for a period of 60 days)
- *Hamsapathyadi kashaya* (15ml + 60ml luke warm water ,45 minutes before food, twice daily for 60days)

Follow up: 4 months (120 days)

Assessment criteria:

1. Thyroid Function Test (objective)
2. Zulewski's clinical score for Hypothyroidism (subjective)
3. QOL with Nottingham Health Profile [8](subjective)

These were observed and statistically analyzed on 0th, 60th and 180th days.

RESULTS

Grouping by Prakriti

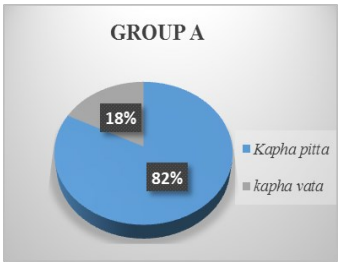


Chart No.1

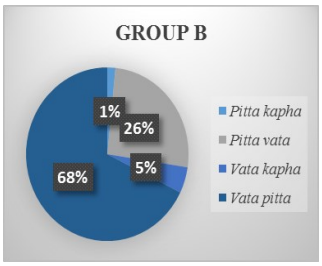


Chart No.2

Demographic Data: Gender

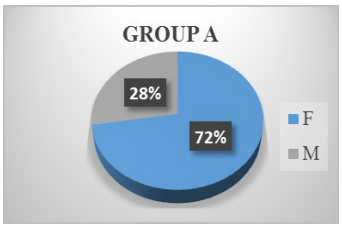


Chart No.3

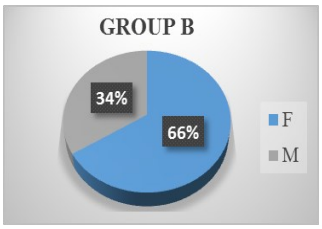
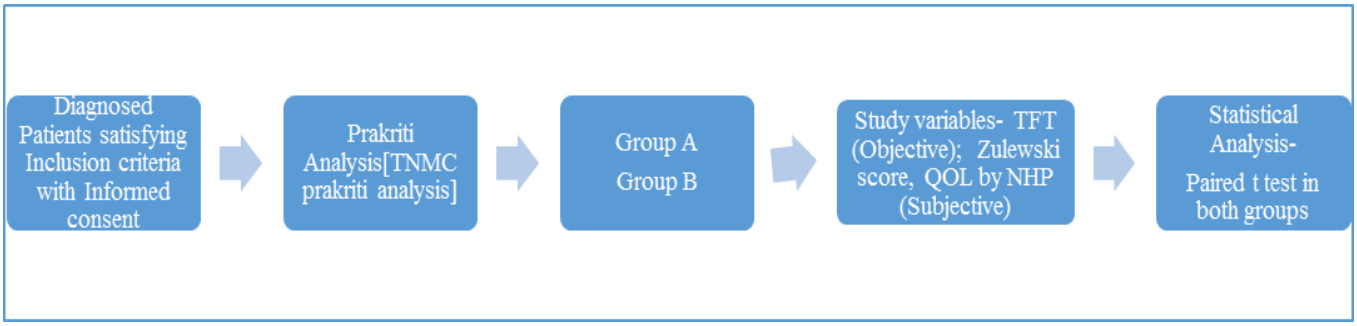


Chart No.4

Figure 1 – FLOW CHART- STUDY PLAN



Clinical Data

Group A - Thyroid Function Test

Table No.2 - Group A - Thyroid Function Test values (*BT- Before treatment(0th day) , AT- After treatment(60th day) , AF - After follow up(180th day)
Normal range: T3:-80-220ng/dL,T4:-5-12µg/dL

Group A	Mean			SD			T value	Sig
	BT	AT	AF	BT	AT	AF		
TSH	6.63	6.43	6.4	2.47	2.551	2.53	*(BT-AT) 2.08	0.04
							*(BT-AF) 2.47	0.02
T3	115.03	117.2	116.15	17.86	17.77	17.26	(BT-AT)-2.708	0.10
							(BT-AF)-1.958	0.06
T4	6.95	6.98	6.95	1.58	1.6	1.66	(BT-AT)0.33	0.74
							(BT-AF)0.00	1.00

Group B - Thyroid Function Test

Table No.3 - Group B - Thyroid Function Test values;

Group B	Mean			SD			T value	Sig
	BT	AT	AF	BT	AT	AF		
TSH	6.99	6.84	6.8	2.89	2.93	2.88	(BT-AT) 1.24	0.22
							(BT-AF) 2.23	0.03
T3	113.05	112.28	110.29	22.97	22.37	22.27	(BT-AT)0.41	0.68
							(BT-AF)1.38	0.17
T4	7.43	7.43	7.38	2.39	2.17	2.37	(BT-AT)0.45	0.99
							(BT-AF)0.55	0.58

Table No. 4 Zulewski's clinical score for Hypothyroidism – Group A And B

Zulewski's score	Mean			SD			T value	Sig
	BT	AT	AF	BT	AT	AF		
Group A	6.5	2.85	1.28	0.93	1.83	1.32	(BT-AT) 12.69	0.001
							(BT-AF) 24.16	0.001
Group B	6.61	3.21	1.71	1.69	1.68	1.37	(BT-AT)14.34	0.001
							(BT-AF) 20.08	0.001

Zulewski's clinical score range:-0-12

Table No. 5 *QOL-Quality of Life based on Nottingham Health Profile[6 subareas]

Group A	Mean			SD			T value	Sig
*QOL	BT	AT	AF	BT	AT	AF		
Energy level	0.85	0.95	1	0.36	0.22	0.00	(BT-AT)-1.43	0.16
							(BT-AF) 2.62	0.01
Pain	0.88	0.98	1	0.34	0.58	0.00	(BT-AT)-2.08	0.04
							(BT-AF)-2.36	0.02
Emotional reaction	0.88	1.00	1.00	0.34	0.00	0.00	(BT-AT)-2.36	0.02
							(BT-AF)-2.36	0.02
Sleep	0.8	0.92	0.98	0.27	0.18	0.09	(BT-AT)-2.90	0.001
							(BT-AF)-4.24	0.001
Social Isolation	0.9	0.95	1.00	0.17	0.15	0.00	(BT-AT)-1.72	0.09
							(BT-AF)-3.66	0.01
Physical abilities	0.86	0.98	1.00	0.18	0.06	0.00	(BT-AT)-4.39	0.0011
							(BT-AF)-5.15	0.00

score 0 :poor health ; 1:good health

Table No.6- QOL-Quality of Life based on Nottingham Health Profile [6 subareas]

Group B	MEAN			SD			T value	Sig
QOL	BT	AT	AF	BT	AT	AF		
Energy level	0.45	0.89	0.98	0.37	0.27	0.12	(BT-AT)-7.73	0.001
							(BT-AF)10.85	0.001
Pain	0.78	0.91	0.99	0.2	0.19	0.06	(BT-AT)-3.99	0.001
							(BT-AF)-7.45	0.001
Emotional reaction	0.78	0.96	0.98	0.2	0.19	0.06	(BT-AT)-7.43	0.001
							(BT-AF)-8.14	0.001
Sleep	0.71	0.91	0.97	0.29	0.19	0.14	(BT-AT)-4.87	0.001
							(BT-AF)-5.94	0.001
Social Isolation	0.91	0.95	0.99	0.19	0.15	0.05	(BT-AT)-1.97	0.05
							(BT-AF)-3.25	0.02
Physical abilities	0.79	0.92	0.99	0.17	0.11	0.02	(BT-AT)-7.18	0.001
							(BT-AF)-9.28	0.001

DISCUSSION

The concept *prakriti* always remain as an inseparable part in Ayurvedic treatment principle. The combination of *dosha* predominance of the disease and the *prakriti* of the patient plays a vital role in determining the medications as well as prognosis in Ayurveda. As already been found in various prevalent studies on Hypothyroidism, there was a predominance of female participants in this study in both the groups. Taking note of *prakriti*, among the Group A participants, 82% belonged to *Kapha pitta prakriti* and among Group B participants, 68% were *Vata pitta prakriti* . weight gain, constipation, tiredness and dry skin were the most common symptoms presented by the patients. Quality of life was badly effected in majority of the patients in the study.

In the study, Primary Hypothyroidism is dealt as a disease with *kapha-vata-medo vikriti* and *dhatvagnimandhya*. *Kapha dosha vikriti lakshanas* like *gourava, avasada, atinidra, shaithyatha, vata dosha vikriti lakshanas like vaakpaarushya, gaadavarcha and medo dhathu vikrithilakshanas like udara parshwa vridhi* parallels with the symptoms of Primary hypothyroidism. The formulations used in the study in both the groups are with properties which counters with *kapha-vata dosha dushti* and *medo dhathu dushti lakshanas*. The concept of *Galaganda* described by *Acharyas* are generally taken in consideration while treating Hypothyroidism, but the features of *Galaganda* places a close resemblance with thyroid swellings and goiters. Such swelling may not be present in all cases of Hypothyroidism, so symptomatic treatment giving prior importance to the vitiated *doshas* and *dhathus* is used in the treatment of the disease in the study. Moreover *prakriti* analysis of the patients helped in the specificity of the medicines given to them. The properties possessed by the drugs used in the study included *Agni deepana, pachana, Kapha-medo haratvam* , these effectively provided symptomatic relief to the patients and improve their quality of life.

The formulations used were *Hamsapathyadi Kashayam* with *Ballathaka lehya* in participants with *Kapha* dominant *prakriti* and *Hamsapathyadi Kashyam* with *Kanchanaraguggulu* in participants with other *prakriti* except *kapha* dominant. *Hamsapathyadi Kashayam* is typically indicated in *galaganda* and *gandamala* as per the text Bhavaprakasha. The drug *Hamsapadi* is anti-inflammatory and cures swellings and the drug as such is used in the treatment of Hypothyroidism traditionally. The drugs *vasa* and *guduchi* possess anti-inflammatory property and restores *dosha* balance. In 2002, researchers from Indore have already established the effect of neem extracts in Hypothyroidism in rats[9]. Neem is one among the ingredients of *Hamsapathyadi Kashayam*. Another ingredient in *Hamsapathyadi Kashayam* is *Pippali,*the action of which as an adjuvant in the treatment of Hypothyroidism has already been studied[10].

DISCUSSION ON STUDY GROUP:

GROUP A

Group A consisted of 40 patients and were given *Hamsapathyadi kashaya* along with *Ballathaka lehya*. *Bhallathaka lehya* which was given to Group A participants consists of *Ballathaka* and *pathya* which are basically with *kapha hara* property. *Ballathaka* possess strong *Kapha hara* property and can effectively act on a *kapha* dominant disease affected to a person with *Kapha* dominant *prakriti* .The statistical analysis data shows that the Thyroid function test values of Group A patients before treatment, after treatment and after follow up belongs to the category of sub clinical hypothyroidism. TSH value shows statistical significance but it can also be noted that the values have not attained a normal range. This can be due to short duration of the study, Further smaller sample size could have also influenced the statistical results. T3 and T4 values did not show statistical significance in the results. A noted reduction in the scores can be seen in subjective criteria Zuwelski's score and Nottingham Health profile showed an overall good health status after treatment and after follow up. This highlights the efficacy of ayurvedic formulations in maintaining the quality of life of the participants. This itself can be considered as an interesting and favorable outcome of the study.

GROUP B

Group B consisted of 62 patients and were given *Kanchanaraguggulu* along with *Hamsapathyadi Kashaya* . The composition of *Kanchanaraguggulu* is basically *Kapha medohara,* and straightly indicated for *Galaganda.* Besides that, the presence of *triphala* makes it suitable for *vata* and *pitta dosha* coupled with *Kapha dosha.* TSH value showed statistical significance only in the paired comparison of before treatment and after follow-up. Moreover, the subjective criteria used in the study which includes the Zulewski's score and NHP showed significant results as in Group A .T3 and T4 values did not show statistical significance in the results as in Group A .

Conclusion

Prakriti plays an important role in selection of Ayurveda intervention in Primary Hypothyroidism. As already said in mild or subclinical Hypothyroidism there is an increase in the TSH value but the free thyroid hormones remain unchanged. The insignificance in the analysis of T3 and T4 values of both groups concretes the nature of sub clinical Hypothyroidism and the effect of Ayurvedic formulations in its treatment. Moreover, the subjective criteria used in the study which includes the Zulewski's score and NHP showed significant results in both groups. This highlights the efficiency of Ayurvedic formulations in improving quality of life of patients suffering from Primary Hypothyroidism. Smaller duration and sample size can be considered as limitations of the study. Future studies can be done stressing on these Ayurvedic formulations specifically in sub clinical hypothyroidism with longer duration and sample size.

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