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Research Article

TRIKATU CHURNA IN THE MANAGEMENT OF HYPOTHYROIDISM

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ABSTRACT

Thyroid disease especially Hypothyroidism is one of the commonest endocrine disorders worldwide and its prevalence of is increasing day by day. In allopathic system hypothyroidism is managed by replacement therapy with L-thyroxin which appears effective in restoring biochemical euthyroidism. However, studies continue to show problems in the management of this condition. Many patients report not feeling well with persistent symptoms despite adequate T_4 replacement therapy. It has become necessary to find alternative medicine for managing hypothyroid symptoms. The main underlying pathology in Hypothyroidism is Hypometabolism in the tissues. This hypometabolism can be correlated to *Mandagni* in Ayurveda. Keeping this in mind we can plan the treatment of hypothyroidism in the line of treatment of *Mandagni*. In the treatment of *Mandagni*, on effective Ayurvedic formulation is *Trikatu Churna*. In this clinical study we have used *Trikatu churna*, as a dietary supplement in 30 patients from the OPD of Govt. Ayurvedic College and Hospital, Guwahati, to study its potential in the management of hypothyroidism. The statistical analysis of the data in trial group with *Trikatu churna* showed the value at 1.86 with level of significance at 1% ($p<0.10$). The Result of the clinical trial signifies that *Trikatu churna* is effective in the management of hypothyroidism.

KEYWORDS: Hypothyroidism, *Mandagni*, *Trikatu churna*, clinical symptom, biochemical euthyroidism.

INTRODUCTION

Thyroid disorders mainly Hypothyroidism is a very common problem amongst the general population worldwide and in India as well. It has been reported that in India alone about 42 million people suffer from thyroid disorders[1]. The growing cause of concern is that the incidence is increasing day by day.

Hypothyroidism is a disease involving the thyroid gland where there is hypo-functioning of tissue metabolism. Diagnosis and treatment of hypothyroidism is often considered simple with hormone replacement therapy. However, studies continue to show problems in the management of this condition. Many patients on thyroid hormone replacement are either under-replaced or over-replaced[2]. A significant number of patients on thyroid hormone replacement report not feeling well with persistent symptoms despite adequate T4 replacement therapy and thyroid hormone level within normal limit. Most often the symptoms of hypothyroidism like weight gain, lethargy, fatigue, muscle aches, depressed mood, decreased memory function, hair fall etc. persist in the patient [3]. A recent community study provided evidence to indicate that patients on thyroxin replacement even those with a normal serum TSH display significant impairment in psychological well-being compared with controls of similar age and sex. [4]

In the Ayurvedic classics there is no direct mention of the disease hypothyroidism. A passing reference to the disease *Galaganda* compared with goitre is found in most of them. Another possible correlation is the disease *Kaphaja Soth* which has features similar to myxedema. Since in Hypothyroidism the main underlying pathology is hypometabolism, it seems to fit into the concept of *Mandagni* given in *Ayurveda*.

However, as regards to treatment of hypothyroidism, there is no specific and effective classical medicine. Apart from *Kanchanar guggulu*, there seems to be no other choice.

To overcome this lacuna in this clinical study we have used *Trikatu churna* as a dietary supplement to find out its potential in the management of hypothyroidism correlating the concept of hypo metabolism in hypothyroidism with *Mandagni.*

STUDY DESIGN

The study design is a randomized control trial cleared by the Institutional Ethical Committee, Govt. Ayurvedic College. A total no of 60 patients of hypothyroidism were randomly selected from the OPD of Govt. Ayurvedic College and Hospital, Guwahati-14, Assam, India after scrutinizing the inclusion and exclusion criteria as mentioned below.

Inclusion criteria: All hypothyroid patients with TSH level ≤ 10mlU/L. Patient of any sex, religion community, socio-economic status, education and age who satisfy the required criteria and willing to take part in the trial.

Exclusion criteria: Critically ill patients.

The patients were divided into 2 groups of 30 patients each.

A) Group A: *Trikatu churna* as a supplement with diet of the patient along with dietary advice specific for hypothyroidism.

B) Group B: conventional treatment with thyroxine sodium (1.6µgm/kg/day).

MATERIALS

i) Consent form,

ii) Performa (case record form)

iii) *Trikatu churna* : equal quantity of -

a) *Pippali - Piper longum*

b) Marich – Piper nigrum

c) Sunthi – gingiber officinalis

METHOD

A detailed clinical examination was done before and after the study using a prepared case record form. The patients in group A are advised to take the trial supplement *Trikatu churna* (1½ - 3gms) mixed with their regular meal like dal, sabji etc. with additional dietary advice specific for hypothyroidism. The patients in group B are prescribed conventional treatment with levothyroxine sodium in appropriate dose (1.6µgm /kg/day).

Trial supplement	*Trikatu churna (sunthi+ pippali+ marich*, in equal quantity)
Quantity	$1^{1}/_{2}$ - 3gms
Duration of study	90 days

Criteria for assessment of result

The selected patients in both the groups are advised to take their respective treatment advice and asked to come for follow up every 30 days till the entire study duration of 90 days. The result is assessed on the basis of Objective parameter before and after the treatment.

Objective parameter:

1. Estimation of serum TSH level.
2. Estimation of T^3
3. Estimation of T^4

RESULT

During the study, the patients were first screened for their thyroid profile (TSH, T_3 & T_4) and the result recorded. After 90 days of treatment, the thyroid profile of the patients was assessed again. It was observed that in group A, where *Trikatu churna* was given as supplement with diet, the patients regained euthyriod state i.e., their TSH level came down to within normal limits. Along with it the associated symptoms of Hypothyroidism like weight gain, constipation, indigestion, lethargy, fatigue, muscle aches, depressed mood, was also relieved to a great extent. In group B, where levothyroxine sodium in appropriate dose (1.6µgm/kg/day) was given, the euthyrid status was achieved but symptoms associated with hypothyroidism remained in most of the patients. The T^3 and T^4 value before treatment was within normal limits in most of the patients and didn't show significant change after treatment and was within normal limits. Comparison of the efficacy of treatment in both the groups showed that *Trikatu churna* is less effective than levothyroxine in achieving the euthyroid state. But, it is undoubtedly an effective replacement for levothyroxine keeping in mind its effect in relieving the associated symptoms of hypothyroidism.

The statistical analysis of the data to study the efficacy of treatment is as below:

Table 1: Effect of treatment in trial group (Group A)

Group	n	Mean(X)	SD	SE	T value	P value
A	29	1.75	5.04	0.94	1.86	<0.10

The statistical analysis of the data in trial group with *Trikatu churna* (Group A) showed t value at 1.86 with level of significance at 1% ($p<0.10$) signifying that the efficacy of treatment in the trial group is significant.

N.B: The sample size in the trial group though initially was taken as 30, 1 sample had to be omitted while doing the statistical analysis as its inclusion showed aberrant results. So for the analysis of the data with paired t –test in Group A, sample size (n) was taken as 29.

Table 2: Effect of treatment in control group (Group B)						
Group	**n**	**Mean(X)**	**SD**	**SE**	**t value**	**P value**
B	30	4.74	3.34	0.61	7.8	<0.01

Analysis of the statistical data in the control group with hormone replacement therapy (Group B) showed t value at 7.8 with level of significance at 0.1% ($p<0.01$). Thus it is seen that the efficacy of treatment in the control group is highly significant.

Table 3: Comparison of effect of treatment in trial group (Group A) and control group (Group B)							
Group	**n**	**Mean(X)**	***df***	**Combined variance of SD**	**SE**	**t value**	**P value**
A	29	1.75	57	4.2	1.1	-2.99	<0.01
B	30	4.74					

Comparison of the statistical data of the two groups gives the t value at 2.99 corresponding to a P value <0.01. Thus it can be inferred that the efficacy of treatment in the control group with hormone replacement therapy (Group B) is more significant than in the trial group with *Trikatu churna*.

DISCUSSION AND CONCLUSION

From the clinical trial done with *Trikatu churna* on patients of Hypothyroidism, positive response has been obtained. The result observed in the patients in the clinical trial it has shows that *Trikatu churna* reduces body weight, puffiness from eyes, increases the digestive capacity. Patients also experienced decrease in lethargy and feeling of heaviness. In all the 30 patients there is a considerable decrease in the TSH level as well.

Trikatu is an effective formulation in treating *Mandagni*. This has been mentioned in the classical texts of Ayurveda by various scholars.

Trikatu churna is an Ayurvedic poly herbal preparation of *Pippali* (*Piper longum* L., fruit), *Marich* (*Piper nigrum* L., fruit) and *Sunthi* (*Zingiber officinale* Rosc, rhizome), all in equal ratio. It is one of the most commonly used ingredients in most Ayurvedic formulations. Synonyms of *Trikatu* include *Katutrik, Triusan, Vyos*. According to *Vhabprakash Trikatu* increases *Agni*, relieves respiratory disorders, skin disease, *Gulma, Prameha, Kapha, Sthoulya, Meda, Slipad* and *Pinas.* [5]

Trikaṭu is predominantly having *Uṣṇa, Tikṣṇa, Laghu, Ruksa guṇa, Kaṭu rasa, Kaṭu vipaka* & *Uṣṇa virya*. Hence it exhibits *Kapha-vata shamaka*, *Deepana, Pachana, Srotovishodhana* & *Shothahara* properties. In *Ayurvedic* tradition, *Trikatu* is known as Heating Formula. Its Thermogenic action or *Usna guna* promotes *Agni* or digestive fire which burns the harmful toxins and revitalizes the metabolism. Some important benefits of *Trikatu* are: it promotes healthy digestion, improves all gastric functions, and increases food absorption. It reduces congestion in digestive tract. It is recommended for poor digestion and poor appetite. It is also recommended for improving lung functions. It helps in reducing excess weight and increases vitality etc. *Sunthi* is one of the best herbs which rejuvenate the whole body, this is the reason it is also called as *Vishvabhaishjya* which means the medicine of the world. *Maricha* or black pepper is said to have *Pramathi Guna* i.e., it forcefully expels out the toxins from the body [6,7,8]. *Pippali* increases the absorption of selenium, a trace element required for deiodinase reaction of the thyroid hormone necessary for bioactivity of the hormone [9].

The active principle of *Trikatu* is piperine. Piperine (1-piperoyl piperidine), an amide alkaloid, is mainly responsible for enhancing the bioavailability of concurrently administered drugs. This mechanism is still being studied, but piperine is known to inhibit the enzymes P-glycoprotein and CYP3A4 in humans. These enzymes are involved in the metabolism and transport of various metabolites [10]. Piperine interacts with proteins embedded in the cell membrane by stimulating leucine amino peptidase and glycyl-glycine dipeptidase activity. This suggests that piperine could modulate the cell membrane dynamics related to passive transport mechanism due to its apolar nature by interacting with surrounding lipids and hydrophobic domain of cellular proteins. The improved bio availability of nutrients by the piperine is perhaps due to its thermo nutrient action or thermogenic action. Bioavailability enhancing action of drugs is partly due to enhancement of blood supply in enteric vessels as a result of local vasodilatation by enhancing drug transport [11].

Analysing the properties of *Trikatu churna*, it can be concluded that the possible mode of action of the trial drug *Trikatu churna* may be due to its property of thermogenesis and its action as bioavailability enhancer. According to *Ayurveda* also the *Usna guna* and *Katu rasa* of *Trikatu* stimulates *Pitta*. It has predominance of *Agni, Vayu* and *Akash*

mahabhut which is responsible for *Kapha saman*. It has *Deepaniya* and *Pachaniya* property and it promotes *Agni*. Besides the *Tikshna* property of *Trikatu* ensures tissue penetration thereby showing its action in *Mandagni* at the *Dhatwagni* and *Bhutagni* level. So in hypothyroidism where there is hypometabolism, *Trikatu churna* shows promising results by reversing the hypometabolism in the tissues and thereby, by feedback mechanism normalising the TSH. Thus *Trikatu churna* can be used as a dietary supplement in the management of hypothyroidism. However further research is required to study how *Trikatu churna* enhances metabolism in the tissues effecting the thyroid hormone levels.

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