



Clinical Study To Evaluate The Efficacy Of *Punarnavadi-Kanamula Yoga* (Hypothetical) In Hypothyroidism

Hrishabh Datt Sharma,¹ Indumati Sharma²

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- 1- P.G Scholar, P.G. Department Of Kaya Chikitsa, M.M.M. Govt. Ayurveda College Udaipur
- 2- Associate. Prof. P.G. Department Of Kaya Chikitsa, M.M.M. Govt. Ayurveda College Udaipur

Corresponding Author :- Hrishabh Datt Sharma, P.G Scholar, P.G. Department Of Kaya Chikitsa, M.M.M. Govt. Ayurveda College Udaipur, Email,Id- hrishabh030894@gmail.com

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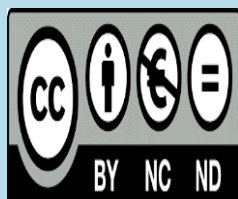
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ABSTRACT: -

Today's era is all about psycho-somatic diseases. These intimate affections of mind & fast moving society have disturbed the psychosomatic structure of human beings which has led to various disorders e.g. hypertension, diabetes, ulcerative colitis and various endocrine related abnormalities. Modern era is influencing both body & mind status of the individual. Pathogenesis of hypothyroidism according to the principles of Ayurveda, we find ourselves around the fact that it is basically related to *Agni*. *Dhatwagni* is effected adversely due to influence of malfunctioning *Jhataragni* formed in the pathology of disease hypothyroidism. Hypothyroidism is a metabolic disorder in its net result, there is nothing wrong in comparing with the "*Agnimandhya*" principle of Ayurveda.

Key Words: Ayurveda, Hypothyroidism, *Agnimandhya*, Thyroid disorders.



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INTRODUCTION

In the changing and busy life schedule of 21st century, Hypothyroidism is considered one of the most common disease. It is caused due to the low thyroid hormone level in the blood. Here the thyroid gland fails to produce enough level of thyroid hormone to undertake the metabolic activities of the body. Thyroid gland produce hormone namely Thyroxine (T4) and Tri-iodothyronine (T3) are involved in all the metabolic procedure of the body and regulates all the function of most of the organs. In the normal situation, the thyroid gland releases 100 - 125 nmol of thyroxine (T4) daily and only little amounts of tri-iodothyronine (T3). The half-life of T4 is approximately 7-10 days. T4 is a prohormone and T3 is active form of thyroid hormone. T4 is converted to T3 by 5'-deiodination in the peripheral tissues. In the Early stage of disease compensatory mechanisms maintain T3 levels. Pituitary gland increases the tsh level when production of T4 decreases. Thyroid stimulating hormone stimulates hypertrophy and hyperplasia of the thyroid gland. It also stimulates de-iodination process and this causes the thyroid to release more T3. Metabolically active cells of the body require thyroid hormone and effect of hormone deficiency vary. [1],[2],[3]

In the *Ayurvedic* texts, hypothyroidism is not mentioned as a disease directly, but its symptoms can be found similar to many diseases mentioned in *Ayurveda* like *Kapha Sotha*, *Kapha Galaganda* etc. Hypothyroidism shows more similarity with the *Kaphaja Sotha* in its sign and symptoms which is mainly mentioned by *Charak*. Since Hypothyroidism is a metabolic disorder in its net result, it is adequate to compare it with the “*Agnimandya*” principle of *Ayurveda* [4].

Agnimandya is considered as a major cause for every disease in *Ayurveda*. It is mentioned “*Roga sarvapi mandagno*” highlighting the importance of Agni in the *Ayurvedic* texts. *Agnimandya* is found at the level of *Jatharagni*, *Bhutagni* and *Dhatwagni* which can be correlated to hypothyroidism from called to systemic levels in modern terminologies. Hypothyroidism is considered to be *Tridoshaja* according to *Ayurvedic* view. Major features like weight gain, hoarseness of voice, depression, cold intolerance point out to its *Kaphaja* predominance along with its *Rasa Dhatu* involvement which is reflected in its symptoms like *Aruchi*, *Tandra*, *Pandu*, *Agnimandya*, *Srotorodha* etc. [5],[6],[7]

AIMS AND OBJECTIVES

1. To study etiopathogenesis of hypothyroidism and to explore the clinical consequences in the light of *Ayurvedic* principles.
2. To assess the role of *Punarnavadi-Kanamula Yoga* in the management of hypothyroidism.
3. To find out an effective and safe remedy for hypothyroidism.

MATERIALS AND METHODS

Source of data

- A. Literary source** - Basic information's on the disease regarding its etiology, pathophysiology, clinical symptoms, prognosis and treatment principles are included in the literary review from the perspective of both *Ayurvedic* and modern view.
- B. Patient source** - The study included 30 clinically diagnosed hypothyroidism patients who were seen in the OPD and IPD of the Govt. *Ayurveda* Hospital, Udaipur, which is affiliated with M.M.M. Rajasthan *Ayurveda* College, Udaipur,

regardless of their religion, age, sex, , occupation, or other factors.

C. Informed Consent - The participants of the clinical trial was given full clarification regarding the structure of study and signed consent was obtained before their involvement in the study.

D. Selection Criteria –

1. Unexpected weight gain, constipation, hoarseness of speech cold aversion, exhaustion, oedema and depression are among the symptoms reported by participants.

2. Age range: 20 to 60 years old.

3. TSH levels greater than 5 mIU/L were detected in the subjects.

E. Exclusion Criteria-

1. Thyroid disease is being monitored, and there is a history of pituitary or adrenal disease.

2. Thyroid abnormality in pregnancy will be excluded.

3. People who were born with hypothyroidism.

4. People who have been diagnosed with a thyroid tumour.

5. Hypothyroidism as a result of surgery.

F. Criteria For Withdrawal -

1. If any medical illness or serious adverse effects arise during the trial, they must be treated immediately.

2. The subject expresses a desire to withdraw from the clinical trial.

G. Laboratory Investigations:

Thyroid Function Test

SerumT₃,

SerumT₄,

Serum TSH (Thyroid Stimulating Hormone)

H. Study Design -

Single study

Randomized

Interventional type

Efficacy study

Drug And Posology:

Drug	<i>Punarnavadi - Kanamula Yoga</i>
Dose	3 gm churna twice a day
Duration	2 month
Anupana	Luke warm water

Contents of drug:^{[8],[9],[10],[11],[12]}

S.No.	Sanskrit name	Botanical name	Part used	Quantity
1.	<i>Punarnava</i>	Boerhavia diffusa	Whole plant	1 part
2.	<i>Shunthi</i>	Zingiber officinalis	Rhizome	1 part
3.	<i>Nishoth</i>	Operculina terpepethum	Root bark	1 part
4.	<i>Guduchi</i>	Tinospora cordifolia	<i>Kand</i>	1 part
5.	<i>Amaltas</i>	Cassia fistula	<i>Phal majja</i>	1 part
6.	<i>Haritaki</i>	Termenelia chebula	Fruit	1 part
7.	<i>Devdaru</i>	Cedrusdeodara	<i>Kand Sar</i>	1 part
8.	<i>Pippali Mool</i>	Piper longum	Root	1 part

Follow Up Study:

- The clinical trial lasted for 60 days.
- Every 15 days, all of the trial's patients were re-evaluated for 2 months.

ASSESSMENT CRITERIA:

The signs and symptoms of hypothyroidism were added to a special proforma, and a standardized scoring system for the signs and symptoms was

used by *Ayurvedic* and Modern guidelines for evaluating the results.

1. Subjective parameters

2. Objective parameters

1. SUBJECTIVE PARAMETERS: To subjectively measure the effect of therapy, all signs and symptoms will be rated according to their severity

Parameters		Scores
1. Tiredness	No tiredness	0
	Mild tiredness after exertion	1
	Tiredness without exertion	2
	Tiredness increases with exertion and routine work	3
	Unable to do routine work	4
2. Weakness	No weakness	0
	Mild weakness but not enough to hamper routine work	1
	Can do routine work with effort	2
	Requires help to do routine work	3
	Unable to do routine work	4
3. Constipation	Normal bowel habit	0
	Passes stools daily but with slight difficulty	1
	Passes hard stools on alternate days	2
	Patients need some laxative to pass stool	3
	Unable to pass stool even after use of laxative	4
4. Dyspnoea	No troubled by shortness of breath on level or uphill	0
	Troubled by shortness of breath on level or uphill	1
	Walks slower than person of same age	2
	Stops after walking 100 yds. Or after few minutes on level ground	3
	Too breathless to leave the house or breathless on dressing or undressing	4
5. Hoarseness of	Normal voice	0
	Patient feels that his /her voice is changing	1

voice	Hoarseness of voice	2
	Changes in voice pronounced	3
	Slurred speech	4
6. Cold intolerance	Absent	0
	Cold intolerance especially with environmental changes	1
	Cold intolerance present in spite of clothing, avoids cold climate	2
	Disability present even on normal room temperature	3
	Susceptible to even mint temperature fluctuations.	4
7. Menstrual abnormalities	Normal menstrual cycle	0
	Oligomenorrhea present from 35 day	1
	Oligomenorrhea present from 35-45day	2
	Oligomenorrhea present from 45-55day	3
	Oligomenorrhea present above 55 day	4
8. Dry coarse skin	Normal skin	0
	Mildly dry skin	1
	Dryness reduced by application of some lubricant cream	2
	Dryness persist even after application of lubricant cream	3
	Complete loss of elasticity with scaling and dryness of skin	4
9. Swelling all over body	Absent	0
	Mild swelling over the body present (Pat.feel heavy body)	1
	Moderate swelling all over the body present with periorbital puffiness	2
	Severe swelling all over the body with periorbital puffiness	3
	Agonizing swelling all over body with puffy face	4
10. Hair loss	No	0
	Mild	1
	Moderate	2
	Severe	3
	Agonizing	4

RESULTS

The data obtained in clinical study is subjected to statistical tests and analyzed in three parts as:

1. Subjective Criteria
2. Objective Criteria
3. Overall effect of therapy

1. SUBJECTIVE CRITERIA

- A) In this clinical study, the percentage of improvement in each parameter of each scale is calculated.
- B) The subjective parameters are analyzed after evaluating the difference in the B.T. & A.T using Wilcoxon signed-rank test.

Variables	Mean B.T.	Mean A.T	Mean Diff.	%	'W'	'N'	'P'
TIREDNES	2.633	0.7667	1.867	70.88608	435.00	29	< 0.0001
WEAKNESS	2.233	0.6000	1.633	73.13433	399.00	28	< 0.0001
CONSTIPATION	2.516	0.5161	2.000	79.48718	253.00	22	< 0.0001
DYSPTNOEA	1.700	0.6000	1.100	64.70	253.00	22	< 0.0001
HOARSENESS OF VOICE	0.6667	0.3000	0.3667	55	66.000	11	<0.0010
COLD INTOLERANCE	1.167	0.5667	0.6000	51.42857	105.00	14	0.0001
MENSTRUAL ABNORMALITIES	0.6207	0.2759	0.3448	55	28.000	7	0.0156
DRY COARSE SKIN	3.484	1.677	1.806	51.85	253.00	22	< 0.0001
SWELLING ALL OVER BODY	1.633	0.7586	0.9310	55.10204	190.00	19	< 0.0001

OBJECTIVE CRITERIA

Paired 't' test was applied to the following objective parameters.

Ser. TSH

Ser. T3

Ser. T4

Investigation	Mean		Mean	%	S.D.	S.E.	't' value	P value
	BT	AT	D.F.	Change				
T3	0.9007	0.878	0.0224	2.49	0.2388	0.04359	0.5154	0.6102
T4	6.192	6.505	-0.313	-5.0551	0.826	0.1509	2.074	0.0471
TSH	10.939	9.793	1.145	10.4705	1.326	0.2422	4.730	0.0001

OVERALL EFFECT OF THERAPY:

Parameters	No. of patients	Overall relief
Complete improvement	00	00
Marked improvement	04	13.33 %
Moderate improvement	24	80 %
Mild Improvement	02	6.66 %
No Improvement	00	00

It was observed that there was a moderate improvement in 24 (80%) patients, marked improvement in 4 (13.33%) patients and mild improvement in 2 (6.66%) patients out of the study conducted on 30 patients.

DISCUSSION

TIREDDNESS - Tiredness was reduced in 70.88% of the patients and it was statistically considered extremely significant ($p < 0.05$). Due to *Rasa Dhatu Dhusti* prevailing in hypothyroidism tiredness felt as a major symptom. This formulation probably act at the *Jathragni* level and relieve the symptom curing the *Ras dhatu Dhusti*.

WEAKNESS – There was a reduction of weakness in 73.13%. Weakness was due to non nourishment of *Dhatu* due to *Agni* vitiation which is acted upon by this formulation which was statistically significant ($p < 0.05$).

CONSTIPATION - Constipation was reduced in 79.48%. It was caused by *Apan Vayu Dhusti* due to *Avaran* of *Kapha* by its *Manda Guna*. So constipation is relieved by *Deepan*, *Rechana*, *Shrotoshodhaka* and *Pachana* properties of drugs containing in the drug. It is considered extremely significant.

DYSPNOEA- In 64.70% of the patients, dyspnea was relieved, which was caused by *Vata kapha dhusti*. By the *Vatakaphaghna* property of the formulation it reduces dyspnea which is considered statistically significant ($p < 0.05$).

HOARSENESS OF VOICE - *Kapaha dhusti* is considered as the cause for hoarseness of the voice. By *kaphaghna* property the formulation reduces the hoarseness of voice in 55% patient which was considered statistically significant ($P < 0.05$).

COLD INTOLERANCE - In 51.42 % of people there was a reduction in Cold intolerance. This was statistically significant ($P < 0.05$).

MENSTRUAL ABNORMALITIES - The abnormality of *Ras dhatu* caused by the *agni dhusti* also results in the abnormality of the *Updhatu Aartva*. By the *Deepan*, *pachana* action of formulation these abnormalities are cured in 55% of the patient.

DRY COARSE SKIN- Dry skin is caused by *Vata dhusti* due to the *Avarana* by *Kapha*. The formulation by its *Vatakaphagna* property reduces the symptoms in 51.85 patient which is considered extremely significant ($P < 0.05$).

SWELLING ALL OVER BODY- Swelling is due to *Kapha Dhusti* which is counter acted by *Kaphaghna* property of formulation which

reduces the symptom in 55.01% of the patients which is considered statically significant ($P < 0.05$).

HAIR LOSS – Due to the *Agnimandya* there is reduction in *Asthi Dhatu* there by malnourishment of its *Updhatu* hair which resulting in excessive hair loss. The formulation by correcting the *Agni* restores its normalcy, reducing the symptoms in 46.77% which is considered statically significant ($P < 0.05$).

CONCLUSION

From the clinical trial conducted on hypothyroid patients using *Punarnavadi - Kanamula Yoga*, the following conclusions are drawn:

Nidan Parivarjana is the first and important line of treatment in any disease. In case of hypothyroidism irregular food pattern, excessive sleep, mental stress, lack of physical exercise plays the role of *Nidana*.

In hypothyroidism the *Samprapti* leads to vitiation of *Rasa* and *Medo dhatu* finally resulting in *Annavaha*, *Rasavaha* and *Medovaha Srotodusti*.

- ❖ As hypothyroidism involves of chronic *Agni Dusti* and *Ama* formation, *Pachana* is to be done for a long duration in order to attain complete cure along with *Deepana* and *Shrotoshodhanam*.
- ❖ In the management of hypothyroidism *Dosha samya* is to be attained by making use of *Kapha Vata* shaman property of drugs.
- ❖ Due to chronic *Rasavaha Srotodusti* involved in hypothyroidism, human body lacks the energy and enthusiasm to function. As *Rasayana* drugs are found more useful in its management.

- ❖ Efficacy of *Punarnavadi - Kanamula Yoga* in the management of Hypothyroidism was about 61.55% in subjective parameters.
- ❖ After the end of the study, it was found that there was a significant reduction in the subjective parameters and non significant change in objective parameters.

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Conflict of Interest: Nil

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