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Evaluation of Clinical Efficacy of an Ayurvedic Compound in Hyperthyroidism: A Clinical Study

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ABSTRACT

Background: The thyroid hormones are inevitable for development of the body and essential to regulate the metabolism. The diseased state of thyroid gland and its debilitating effects are very common conditions all over the world and it subvene most of the populations. The aim of the study was to evaluate the clinical efficacy of an Ayurvedic compound in the patients of Hyperthyroidism compared to conventional treatment in allopathic medicine system. National Institutes of Ayurveda (NIA), Jaipur conducts various research projects through their different department. A clinical project named "Clinical Evaluation of Efficacy of an Ayurvedic Compound in the Management of Borderline Hyperthyroidism" was approved and conducted through *Kayachikitsa* department of the institute in collaboration with Medicine unit of S.M.S. Medical College and Hospital, Jaipur.

Method: This was a prospective, interventional and OPD level study in which 30 patients who met the following inclusion criteria: 1. Patients having clinical features without complications of Hyperthyroidism. 2. Presence of clinical features and relevant laboratory investigations related to hyperthyroidism, were randomly selected in three groups. The assessment of the results was done on the basis of amelioration in Subjective & Clinical parameters and laboratory findings during 2 months course of the treatment. Statistical method paired 't' test was applied during the analysis of data.

Results: During analysis it was observed that much better results were obtained in the patients of group C who were treated with Ayurvedic compound drug in combination with Anti thyroid drug (Neomercazole) than other group of patients.

Conclusion: Significant clinical improvement was observed in most of signs and symptoms in all groups but improvement was more sound in group C where both Ayurvedic and Allopathic drug were taken. It encourages to scientist for taking responsibility to integrate Ayurvedic system of medicine with allopathic regime to cure such chronic diseases.

KEYWORDS - *Ayurveda, Pitta vriddhi, Vata vriddhi, Kapha kshaya*

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INTRODUCTION

Thyroid diseases are commonest endocrine disorders and the global burden of thyroid patients in the general population is abundant. Population of India is also in its enlacement. According to various studies on thyroid diseases, it has been estimated that about 42 million people in India suffer from thyroid diseases[1, 2]. It occurs much more frequently in women than in man (5:1) usually in the third-fifth decades. Women are 2 to 10 times more likely than men to develop hyperthyroidism[3].

In this disease, over stimulated thyroid gland produces hormones above daily requirement. It has several diverse etiological causes comprised Graves' disease, Thyroid nodules, Thyroiditis, or inflammation of the thyroid, Consuming too much iodine and Overmedicating with synthetic thyroid hormone, which is used to treat underactive thyroid.

Ayurveda is most scientific ancient science has been used to provide treatment to chronic and non communicable diseases in all over world. As anatomical knowledge was not so accurate and update in old days so the description of structures and functions of endocrine glands similar to modern knowledge was not found in any classical Ayurvedic texts. Therefore endocrine disturbances induced disorders were also not described in Ayurvedic texts as such precisely but various pathological conditions that have resemblance to endocrinal diseases are described in Ayurvedic lexicon. The signs and symptoms of thyroid diseases are compared to Ayurvedic diseases like *Galganda*, *Atyagni*, *Bhasmaka* and *Atikarshya*, etc. The signs and symptoms of Hyperthyroidism may be compared to *Pitta vriddhi*[4,5,6,7], *Vata vriddhi*[8,9,10,11,12,13]and *Kapha kshaya lakshana* (symptoms)[14,15,16]. *Kapha kshaya* causes *kshaya* of *Rasa*, *Mamsa*, *Meda*, *Majja* and *Sukra Dhatus*. *Artava* which is *Updhatu* of *Rasa dhatu* also found to be decreased due to *Rasa kshaya* caused by *Kapha kshaya*.

MATERIALS AND METHODS

Selection of Cases: Study was conducted on 30 patients of Hyperthyroidism visited in O.P.D. of National Institute of Ayurveda, Jaipur and Medical unit of S.M.S. Medical College and Hospital, Jaipur.

Inclusion Criteria:

- Patients having clinical features without complications of Hyperthyroidism were selected.
- Hyperthyroidism was diagnosed according to the presence of clinical features and relevant laboratory investigations.

Exclusion Criteria:

- Patients having agonizing and complicated clinical features of Hyperthyroidism were not included.
- Hyperthyroidism due to toxic adenoma, pituitary related (TSH-omas), destruction induced, trophoblastic tumor, ectopic thyroid tissue, thyroid cancer and exogenous hormone were excluded from the study.
- Patients having history of other diseases like diabetes, rheumatoid arthritis, carcinoma, asthma and cardiac disease were excluded from the study.

Selection of drugs: *Madhuyasti* (Glycyrrhiza glabra) roots, whole plant of *Shankhapushpi* (Convolvulus pluricaulis), stems of *Guduchi* (Tinospora cordifolia), roots of *Satavari* (Asparagus racemosus) and roots of *Aswagandha* (Withania somnifera) were taken to prepare medicine. *Ghanasatva* of these herbal drugs was used. 500 mg. of the *Ghanasatva* of the drugs was packed in capsules.

Treatment schedule: 30 clinically diagnosed patients were selected and randomly divided into three following groups:

Group A: In this group, Allopathic Anti thyroid drug (Neomercazole) was given to 10 patients for two months.

Group B: In this group, an Ayurvedic drug in the dosage of 1gm BD was given to 10 patients for two months.

Group C: In this group, both Allopathic Anti thyroid drug (Neomercazole) and Ayurvedic compound drug was given to 10 patients simultaneously for two months.

Criteria of Assessment: Patients of all the three groups were regularly assessed after every 15th day of the trial. Treatment was carried out for two months. Laboratory investigations were carried out before and end of the clinical trial.

During the trial and follow-up, patients were assessed on the following parameters:

- Subjective Improvement.
- Clinical Improvement.
- Laboratory Investigations.

Attempts were made to elicit the subjective improvements produced by the drug, specifically feeling of general well being, mental and physical fitness. For the assessment of clinical improvement and severity of the symptoms, the "Symptoms & Signs Rating Scale" was used. Haematological and serological changes i.e. Serum TSH, S.T3 & T4, S. Cholesterol, Hb percentage (gm %), ESR, TLC, DLC, were recorded in relation to the disease. To find out the significance of the changes results were computed statistically and thereafter conclusions were drawn accordingly. SD and SE of the data have

been evaluated there after p Value was calculated with the help of standard charts on the basis of t value.

OBSERVATION AND RESULTS

Distribution of disease by gender, age and *prakriti*:

It was observed in the study that incidence of Hyperthyroidism was more in female (63.33%) than male (36.67%). Table no. 1 shows the percentage of male and female in enrolled patients.

Table: 1 Gender wise distribution of disease

S.No	Sex	No. of Patients	Percentage
1.	Male	11	36.67%
2.	Female	19	63.33%
Total		**30**	**100.00%**

Distribution of disease age wise:

It was found in the study that the incidence of disease was 40% in the age group of 31 - 40 years and 26.67% in the age group of 41 - 50 years followed by 20% in the age group of 21 - 30 years. Data summarize in Table no. 2.

Table 2 Age wise distribution of disease

S.No	Age group (in years)	No. of Patients	Percentage
1.	20 - 30	6	20.00%
2.	31 - 40	12	40.00%
3.	41 - 50	8	26.67%
4.	51 - 60	0	0.00%
5.	61 and above	4	13.33%
Total		**30**	**100.00%**

Distribution of disease *prakriti* wise:

In Table no. 3 it is depicted that 56.67% patients were found to be of *VataPittaja prakriti* followed by 23.33% cases of *Pitta Kaphaja* and 20% cases of *KaphaVataja prakriti*.

Table 3 *Doshik prakriti* wise distribution of disease

S.No	*DoshikPrakriti*	No. of Patients	Percentage
1.	*Vata-Pittaja*	17	56.67%
2.	*Pitta-Kaphaja*	7	23.33%
3.	*Kapha-Vataja*	6	20.00%
Total		**30**	**100.00%**

Clinical and Pathological observation in three groups:

For the assessment of clinical improvement, the "Symptoms & Signs Rating Scale" was used to assess the severity of Increased appetite, Dyspnoea on exertion, Excessive sweating, Intolerance of heat, Palpitation, Irritability, Sleep disturbance (Insomnia), Hyper-defecation (Diarrhoea), Goiter, Restlessness, Warm skin and Fine tremor. In this scale 0,1,2,3 and 4 number was given to Absent, Mild, Moderate, Severe and Agonizing situation for sign and symptom respectively.

Serological changes in TSH, T3 & T4 were included to assess the patient's condition. Mean difference, SD and SE of the observations were calculated and p values with the help of t values were drawn. Table no. 4, 5 and 6 comprise all data values for selected parameters of all group A, B and C respectively.

Table 4 Pattern of Clinical recovery & Laboratory changes in patients of group A

Sr. No.	Observation	n	Mean B.T.	Mean A.T.	Mean Diff.	S.D.	S.E.	t Value	p value
1.	Increased Appetite	8	2	1	1	0.75	0.26	3.74	< 0.01
2.	Weight loss (kg.)	10	51.2	52.8	1.6	1.67	0.53	3.08	< 0.02
3.	Dyspnoea on Exertion	8	1.87	1	0.87	0.64	0.22	3.86	< 0.01
4.	Excessive Sweating	6	1.83	1.16	0.66	0.51	0.23	2.88	< 0.05
5.	Palpitation	7	2	1.14	0.85	0.69	0.26	3.28	< 0.02
6.	Intolerance of Heat	4	2.25	1	1.25	0.5	0.25	5	< 0.02
7.	Irritability	7	2.57	1.43	1.14	0.89	0.34	3.36	< 0.02
8.	Disturbed Sleep	6	2	1	1	0.89	0.36	2.73	< 0.05
9.	Hyper defecation	5	1.8	0.60	1.2	0.44	0.19	6.00	< 0.01
10.	Goiter	8	2.25	1.5	0.75	0.70	0.25	3	< 0.02
11.	Restlessness	10	1.6	0.9	0.7	0.94	0.3	2.33	< 0.05
12.	Warm Skin	7	2	1	1	1	0.37	2..65	< 0.05
13.	Tremor	8	1.87	1	0.875	0.83	0.29	3.01	< 0.02
14.	Tachycardia (Pulse/Min.)	10	92	85.4	6.6	4.99	1.57	4.17	< 0.01
15.	Serum T4		17.60	14.54	3.06	2.53	0.80	3.78	< 0.01
16.	Serum T3		3.40	2.42	0.98	0.96	0.30	3.23	< 0.02
17.	Serum TSH		0.921	1.33	0.409	0.46	0.15	2.82	< 0.02

Table 5 Pattern of Clinical recovery & Laboratory changes in patients of group B

Sr. No.	Observation	n	Mean B.T.	Mean A.T.	Mean Diff.	S.D.	S.E.	t Value	p value
1.	Increased Appetite	8	2.12	1.37	0.75	0.70	0.25	3	< 0.01
2.	Weight loss (kg.)	10	51.9	52.4	0.50	1.08	0.34	1.47	> 0.1
3.	Dyspnoea on Exertion	9	1.88	1.11	0.77	0.75	0.25	3.08	< 0.02
4.	Excessive Sweating	7	2.286	1.429	0.85	0.69	0.26	3.28	< 0.02
5.	Palpitation	8	2	1.12	0.87	0.76	0.27	3.23	< 0.02
6.	Intolerance of Heat	7	2.57	1.57	1	0.81	0.30	3.2	< 0.02
7.	Irritability	10	2	1	1	0.66	0.21	4.74	< 0.01
8.	Disturbed Sleep	5	2.4	1	1.4	0.54	0.24	5.71	< 0.01
9.	Hyper defecation	3	2	1.33	0.66	0.57	0.33	1.99	> 0.10
10.	Goiter	7	1.71	1.43	0.28	0.48	0.18	1.55	> 0.10
11.	Restlessness	6	1.5	0.50	1	0.63	0.25	3.87	< 0.02
12.	Warm Skin	7	1.57	0.71	0.86	0.69	0.26	3.2	< 0.02
13.	Tremor	6	2.66	1.83	0.83	0.75	0.307	2.7	< 0.05
14.	Tachycardia (Pulse/Min.)	10	87.4	81.4	6	4.89	1.54	3.87	< 0.01
15.	Serum T4		12.03	11.99	0.045	1.61	.51	0.087	> 0.10
16.	Serum T3		3.38	3.36	0.02	0.87	0.275	0.072	> 0.10
17.	Serum TSH		1.44	1.54	0.103	0.59	0.19	0.54	> 0.10

Table 6 Pattern of Clinical recovery & Laboratory changes in patients of group C

S. No.	Observation	n	Mean B.T.	Mean A.T.	Mean Diff.	S.D.	S.E.	t Value	P value
1.	Increased Appetite	8	2	0.33	1.66	0.51	0.21	7.9	< 0.001
2.	Weight loss (kg.)	10	50.58	52.95	2.37	1.43	0.45	5.22	< 0.001
3.	Dyspnoea on Exertion	8	2.25	0.625	1.625	0.53	0.20	8.04	< 0.001
4.	Excessive Sweating	7	2	0.86	1.14	0.69	0.26	4.38	< 0.01
5.	Palpitation	8	2.87	1.125	1.75	0.46	0.16	10.69	< 0.001
6.	Intolerance of Heat	6	2.16	0.667	1.5	0.54	0.22	6.71	< 0.001
7.	Irritability	10	2.2	0.9	1.3	0.48	0.15	8.51	< 0.001
8.	Disturbed Sleep	8	2	0.5	1.5	0.53	0.18	7.9	< 0.001
9.	Hyper defecation	6	2.83	0.83	2	0.44	0.18	10.95	< 0.001

10.	Goiter	6	2.5	1.5	1	0.63	0.25	3.73	< 0.01
11.	Restlessness	8	2	0.625	1.37	0.35	0.12	11	< 0.001
12.	Warm Skin	7	2	0.714	1.28	0.63	0.24	5.35	< 0.01
13.	Tremor	8	2.25	1	1.25	0.46	0.164	7.63	< 0.001
14.	Tachycardia (Pulse/Min.)	10	88.4	81.2	7.2	0.28	0.904	7.96	< 0.001
15.	Serum T4		15.93	12.57	3.36	2.47	0.783	4.288	< 0.01
16.	Serum T3		3.376	2.45	.926	0.70	0.22	4.1	< 0.01
17.	Serum TSH		0.80	1.17	0.376	0.36	0.12	3.15	< 0.02

DISCUSSION

Hyperthyroidism is more common in females than in males and occurs more in 4th and 5th decade of life. Peoples of *VataPittaja prakriti* (in selected patients) were more susceptible for this disease.

Like adaptogen, liquorice helps in the HPA axis function[17] and can help in maintaining the functions of the thyroid glands[18]. In one study it has been evolved that the root extracts of Convolvulus pluricaulis decrease serum concentration of T3 in L-thyroxine induced hyperthyroid mice. These results show that the plant extract regulate the function of thyroid gland (inhibit the level of T4 to T3)[19]. Various studies also show that *Aswagandha* and *Guduchi* have regulating effect on thyroid glands[20, 21].

As per Ayurvedic principles and concepts, the symptoms of Hyperthyroidism manifest the predominance of *PittaVata Dosha* and *Dhatu Kshayatmak Lakshanas*. The contents of selected Ayurvedic compound drug have a combined effect on *Vriddha Vata Pitta* palliation. These drugs also act as *Medhya, Balya, Dahahara, Soshahara, Dhatupostik* etc. therefore helped in improving the body functions.

In group A patients, there was significant improvement in increased appetite, weight loss, dyspnoea, palpitation, intolerance of heat, irritability, hyper defecation, goiter, tremor, and tachycardia and there was mildly significant improvement in symptoms of restlessness, warm skin, excessive sweating and sleep disturbance.

In B group, significant results were observed in some symptoms than group A like excessive sweating, sleep disturbance, warm skin and restlessness.

Improvement in symptoms like increased appetite, dyspnoea, palpitation, intolerance of heat, irritability and tachycardia in group B was same as group A but the percentage of improvements in symptoms of palpitation and irritability was high in Ayurvedic group than group A. The percentage of improvement in dyspnoea and tachycardia was high in group A than group B. It was also observed that the improvement in goiter, weight loss and hyper defecation were insignificant and

mild changes were observed in symptoms of tremor in Ayurvedic treated group. Observations have also revealed that symptoms related to nervous system i.e. sleep disturbance, restlessness and irritability were showed better response to Ayurvedic Drug (Group B) compared to Anti thyroid Drug (Group A).

In group C it was observed that highly significant clinical improvement was found in all symptoms except symptoms like excessive sweating, goiter and warm skin, where only significant improvement was observed. According to relief of percentage, there was more than 70% of improvement in increased appetite, dyspnoea, disturbed sleep, hyper defecation, and almost more than 60% relief in palpitation, irritability, warm skin, and restlessness.

It was observed that group A and group C had significant changes in serum T3, T4 & TSH level than group B.

CONCLUSION

It was observed that all the three groups showed statistically significant and highly significant improvement in various clinical manifestation of Hyperthyroidism. Amelioration in various symptoms of hyperthyroidism was achieved in patients treated by Ayurvedic drugs .As every ingredients of the Ayurvedic drug has more or less pharmacological actions not only on thyroid hormones induced symptoms but on other as well. All these changes made patients feel well. The level of average clinical improvement in group A was 9.76% ($t= 2.55$, $p< 0.02$), which was significant. Average clinical improvement in group B was 9.71% ($t= 2.91$, $p< 0.01$) which was also significant. Similarly average clinical improvement in mixed group i.e. C group was 13.39% ($t= 3.09$, $p< 0.001$) which was highly significant. It may be said that in 30 patients of Hyperthyroidism (in all the three groups) the general feeling of well being was increased as well as symptomatic and pathological changes was improved also. The results showed that the patients of Hyperthyroidism when treated with Ayurvedic compound drug in combination with Anti thyroid Drug (Neomercazole) in patients of group C had highly significant improvements than other group of patients. The challenges in the management of hyperthyroidism still need special attention. As this study showed better amelioration in group C of Ayurvedic drug compound with Allopathic drug, it may said that the appropriate combination of Ayurvedic drugs with Allopathic drugs may ameliorate the symptoms better but still more and more clinical and conceptual works are to be explored in this regards. In developing countries like India, more systematic

studies are required to integrate Ayurvedic system of medicine with established allopathic regime which can be rendered to suit the patient's requirements.

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