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Research Article

A CLINICAL STUDY OF *KANCHANARA PATRA PHANTA* IN MANAGEMENT OF HYPOTHYROIDISM

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ABSTRACT

Hypothyroidism is a common endocrine disorder. Primary Hypothyroidism is up to 8–9 times more common in women than in men, and the prevalence increases with age, with a peak incidence between the ages of 30 and 50 years. According to Ayurveda, this disease is termed as *Galaganda*. Acharya Sushrutha opines that a swelling in the neck, big or small hanging-like scrotum is defined as *Galaganda*; this disease, is characterized by vitiation of Agni along with *Kapha* and *Vata dosha*. Various *Shodhana* and *Shamana chikitsa* have been mentioned for *Galaganda. Kanchanara* (*Bauhinia purpurea* Linn) is one such drug mentioned for the treatment of *Galaganda* by Acharya Bhavaprakasha. As there is an ambiguity about effective and successful treatment for Hypothyroidism due to its varying signs and symptoms, it necessitates finding an effective formulation for treating *Galaganda* (Hypothyroidism). **Aim:** To assess the efficacy of *Kanchanara patra phanta* in Hypothyroidism. **Materials and methods:** This study was a randomized, open labeled, non-controlled, interventional clinical trial with before and after evaluation of data in a single group. A single group of 30 study samples was recruited based on the assessment criteria and study was conducted for a total of 30 days period; Assessment of the condition was done with regular follow-ups of day 1, 15 and 30. **Conclusion:** 30 days (twice daily) of internal administration of *Kanchanara patra phanta* showed highly significant efficacy in pacifying the symptoms and reducing the levels of TSH.

INTRODUCTION

Nature has provided wide range of medicinal plants to which are being used in traditional practices of medications in Ayurveda, Siddha, Unani, folk etc. These plants play a vital role in the health maintenance of the people. The first use of the medicinal plant for health-related issue was recorded 5000 years ago. These medicinal plants are the potential source of many of the modern drugs because the photochemical present in these plants are used as the chemical entities for modern drugs.

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Medicinal plants are used in almost all the Ayurvedic practice of treating numerous diseases, Ayurvedic poly herbal formulation are well known drugs in global herbal drug market. There are so many important medicinal plants in the world, which are of great significant value due to their unique photochemistry and biological activities, and one such plant is *Bauhinia variegate (Kanchanara). Kanchanara* is one of the herbs mentioned in all ancient Sanskrit scriptures. It is one of the best-known herbs for its special properties of mitigating the glandular swelling in the body. *Kanchanara* due to its potent astringent property, effectively dries up the vitiate *Kapha* and *Meda*, and furnishes excellent results. It is commonly called as "mountain ebony or camel's foot". *Kanchanara* botanical name is *Bauhinia variegate* Linn belonging to family Caesalpiniaceae,

basonym the flowers of *Kanchanara* are golden yellow in color. According to Ayurveda, a swelling in the neck, big or small hanging-like scrotum has been defined as *Galaganda*. A morbid excess of *Vata* and *Kapha* brings about changes in the fat *(Medas*) and causes swelling in the neck and around it. In this morbidity, features of the vitiated *Doshas* manifest gradually. This condition is known as *Galaganda*. In modern science, it is correlated to Hypothyroidism. Hypothyroidism is a common disorder. Hypothyroidism is diagnosed biochemically, being over primary hypothyroidism defined as serum thyroid stimulating hormone (TSH) concentration above and Thyroxine concentration below the normal range. Hypothyroidism is a chronic disease associated with deficiency in the thyroid hormone, Thyroxine (T_4) and Triiodothyronine (T_3). According to the time of onset it as divided into congenital and acquired, according to the level of endocrine dysfunction into primary and secondary/ central and according to the severity into severe/ clinical and mild/ subclinical. By some estimates, the population prevalence increases with age and it is nearly tenfold more common in women than in men. Primary Hypothyroidism is up to 8–9 time more common in women than in men, and the prevalence increases with age, with a peak incidence between the ages of 30 to 50 years.

Materials and methods: This study was carried out under the following headings:

Pharmaceutical study:

1Ingredient – *Kanchanara patra* (tea bags)– 1 part, Water - 4 parts

Preparation of medicine:

Kanchanara patra phanta was collected, then collected raw drugs were cleaned well and grinded into coarse powder form. 10 gm of this *Kanchanara patra* powder was separately packed in each tea bags. Good Manufacturing Practices was observed during the process of medicine preparation.

Clinical study:

As this research involved human participants, ethical approval was obtained from Institutional Ethics Committee on 03-05-2022 with **IEC no: SDMIAH/IEC/44/2022**. **Study design:** An interventional study with before and after evaluation in a single group. **Study period:** 30 days. **Sample Size:** 30

Total of 30 patients were enrolled for the study, participated till the completion of the trial and the obtained data was tabulated and analyzed. Majorly female patients in the age group of 20 to 45 years old, belonging to middle class society showed interest in participating in study. Maximum number of patients represented the age group of 20-45 years as these people are at the high risk of thyroid disorder. Out of which 10% were male and 20% were female. Based age group 43% were 30-40 years, 40% were 20-30 years, 17% were 40-50 years. Based on occupation 52% were housewife, 26% were students, 22% were working. Based on food habit 77% were non vegetarian and 23% were vegetarian.

Assessment criteria

Subjective criteria

Assessment of symptoms was done according to the likert scale on Day 1, Day 15 and Later on Day 30, a follow up for assessing the recurrence of symptoms was also carried out. The information gathered was subjected to statistical analysis

Table 1: Subjective criteria assessment

Heading		Grading
Puffiness	• Absent • Occasional • Daily periorbital edema/puffiness in the morning relieved in later part of day • Persistent	0 1 2 3
Edema	• Absent • Edema over lower/upper extremities • Edema over both extremities • Edema all over the body	0 1 2 3
Dry and coarse skin	• No dryness • Dryness after bath only • Dryness all over body but relieved by oil application • Dryness not even relived by oil application	0 1 2 3

Breathlessness	• Absent • Occasional only after strenuous workout • Even on climbing upstairs, but relived by rest • Felt in routine work –bathing, changing cloths	0 1 2 3
Constipation	• Once a day • Once in 2 days • Once in 3 days • Once in more than 3 days	0 1 2 3
Weakness	• Able to exercise without difficulty • Able to do mild exercise • Able to only mild work • Able to mild work with difficulty • Not able to do even mild work • Unable to do day to day routine work	0 1 2 3 4 5
Lethargy	• Doing work satisfactorily with proper vigor in time • Doing work without desire, unsatisfactorily but in time • Doing work without desire, unsatisfactorily, with lot of mental pressure and not in time • Not starting any work in his/her own responsibility, doing little work very slow • Does not have any initiation and not want to work even after pressure	0 1 2 3 4
Fatigue	• Normal Patient like to stand in comparison to walk • Patient like to sit in comparison to stand • Patient likes to lie down in comparison with sitting • Patient likes to sleep in comparison with lying down	0 1 2 3
Muscle ache	• No • Relived by rest • Not relived by rest but relived by external application • Requires external application and internal medication • Present consistently	0 1 2 3 4
Duration of menstrual blood	• 4-7 days • 3days • 2 days • 1day	0 1 2 3
Interval between 2 cycles	• 25-29 days • 35-39 days • 40 -45 days • >45 days	0 1 2 3
Hair fall	• Absent • Hair fall washing • Hair fall on combing • Hair fall on simple stretching	0 1 2 3

Objective criteria

Assessment of TSH level on day 1, day 15 and day 30 was observed. The information gathered was subjected to statistical analysis.

RESULT

SUBJECTIVE CRITERIA ASSESMENT

Before commencement of treatment 40%, patients had varying degrees of **puffiness**. The statistical analysis revealed **68% improvement**. Before commencement of treatment 23%, patients had varying degrees of **edema**. The statistical analysis revealed **85% improvement**. Before commencement of treatment 50%, patients had varying degrees of **dry and coarse skin**. The statistical analysis revealed **80% improvement**. Before commencement of treatment 36%, patients had varying degrees of **Breathlessness**. The statistical analysis revealed **66% improvement**. Before commencement of treatment 23%, patients had varying degrees of **constipation**. The statistical analysis revealed **63% improvement**. Before commencement of treatment 86%, patients had varying degrees of **weakness**. The statistical analysis revealed **63% improvement**. Before commencement of treatment 90%, patients had varying degrees of **lethargy.** The statistical analysis revealed **50% improvement**. Before commencement of treatment 70%, patients had varying degrees of **fatigue**. The statistical analysis revealed **54% improvement**. Before commencement of treatment 76%, patients had varying degrees of **muscle ache**. The statistical analysis revealed **50% improvement**. out of 27 female patients 62%, patients had change in **duration of menstrual blood**. From the day of commencement of treatment, there was approximately 22% improvement by day 15, follow up which did not change on day 30. The statistical analysis revealed **22% improvement**. out of 27 female patients 48%, patients had change **in interval between 2 cycles**. From the day of commencement of treatment, there was approximately 33% improvement by day 15, follow up which did not change on day 30. The statistical analysis revealed **33% improvement**. Before commencement of treatment 86%, patients had varying degrees of **Hairfall.** The statistical analysis revealed **44% improvement**.

Overall improvement in subjective assessment parameters: Overall analysis of assessment parameters showed decline in severity of condition and **60% improvement** in overall assessment parameters. There was no systemic adverse drug effects noted till the end of the study.

Table 2: Showing the t' test results in reduction of symptoms of Hypothyroidism

		Paired Differences					T	df	Sig
		Mean	S.D	S.E	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	Puffiness BT- Puffiness AT	0.567	0.774	0.141	0.278	0.856	4.011	29	<0.000
Pair 2	Edema BT- Edema AT	0.233	0.504	0.092	0.045	0.422	2.536	29	<0.017
Pair 3	Dry and coarse skin BT- Dry and coarse skin AT	0.500	0.572	0.104	0.286	0.714	4.785	29	<0.000
Pair 4	Breathlessness BT- Breathlessness AT	0.333	0.479	0.088	0.154	0.512	3.808	29	<0.001
Pair 5	Constipation BT- Constipation AT	0.233	0.504	0.092	0.045	0.422	2.536	29	<0.017
Pair 6	Weakness BT- Weakness AT	1.000	0.788	0.144	0.706	1.294	6.952	29	<0.000
Pair 7	Lethargy BT- Lethargy AT	0.800	0.484	0.088	0.619	0.981	9.049	29	<0.000
Pair 8	Fatigue BT- Fatigue AT	0.933	0.868	0.159	0.609	1.258	5.887	29	<0.000
Pair 9	Muscle ache BT-	0.433	0.568	0.104	0.221	0.646	4.176	29	<0.000

	Muscle ache AT								
Pair 10	Interval between 2 cycles BT- Interval between 2 cycles AT	0.370	0.492	0.095	0.176	0.565	3.911	26	<0.001
Pair 11	Duration of menstrual blood BT- Duration of menstrual blood AT	0.185	0.396	0.076	0.029	0.342	2.431	26	<0.022
Pair 12	Hair fall BT- Hair fall AT	0.867	0.681	0.124	0.612	1.121	6.966	29	<0.000

OBJECTIVE CRITERIA ASSESMENT

Out of 30 patients, 23% had significant reduction of TSH level, 44% had moderate reduction of TSH level, and 33% had mild reduction of TSH level. Out of 30 patients, 20 patients TSH levels had reached normal range, while 10 patients there was mild decrease from their original value.

Table 3: Showing the 't' test result in reduction of TSH levels

TSH Level		Paired Differences					T	df	Sig
		Mean	S.D	S.E	95% Confidence Interval of the Difference				
					Lower	Upper			
Pair 1	on day 1 - on day 15	1.3870	1.495	0.2730	0.8286	1.945	5.08	29	<0.000
Pair 2	on day 15 - on day 30	1.8383	1.664	0.3039	1.216	2.459	6.04	29	<0.000
Pair 3	on day 1 - on day 30	3.2253	2.749	0.5020	2.198	4.252	6.42	29	<0.000

DISCUSSION

Galaganda is defined as swelling in the neck, big or small hanging-like scrotum; this disease is correlated to Hypothyroidism. Hypothyroidism is defined as serum thyroid stimulating hormone (TSH) concentration above and Thyroxine concentration below the normal range. Hypothyroidism is a chronic disease associated with deficiency in the thyroid hormone, Thyroxine (T4) and Triiodothyronine (T3). These hormones have an influence on metabolic rate, growth, development and reproduction. Common symptoms are decrease in the basal metabolic rate, unexplained weight gain, tiredness etc. which hamper the daily activity of an individual. Hypothyroidism is one such disease most commonly encountered in clinical practice. This condition is most commonly seen in India. 1 in 10 Indians suffer from thyroid disorder; with women being more prone to it (8 out of 10). *Kanchanara* (*Bauhinia purpurea* Linn) is one such drug mentioned for the treatment of *Galaganda*. According to *Phantadi Kalpana* told by Acharya Sharangdhara, *Kanchanara patra phanta* (tea bag) is a modified method of preparation. *Kanchanara* is said to have effective action on *Galaganda*, due to its *Rasapanchaka* (Rasa-*Kashaya, Guna-Laghu, Ruksha, Virya-sheetha, Vipaka-katu, Prabhava-gandamala hara*, *karma- Kapha-pitta shamaka, Gandamala hara*) and pharmacological activity. Statistically there was a decrease in the level of TSH and symptoms of Hypothyroidism. This remarkable result of the selected treatment is due to the mode of action exhibited by drugs and synergistic pharmacological activities over the triggering and causative factors. The chemical constituent present in this drug is said to have anti-inflammatory, anti-infective properties, Antigoitrogenic activity and Immunomodulatory activity. As per Ayurvedic, perspiration the mode of action anticipated here involve *Gandamala hara, Shothahara* that helps in the reduction of the swelling, which is caused by inflammation. Overall, cumulative pharmacological activities of *Kanchanara* are *Shothahara, Galaganda hara*, and *Gandamala hara*, anti-inflammatory and anti-infective properties of *Kanchanara patra*. Based on the results in this study relief with decline in symptoms and reduction in the TSH level. The statistical analysis showed that *Kanchanara patra phanta* is effective in reducing the symptoms of

Hypothyroidism and levels of TSH with significance level <0.05.

CONCLUSION

This study has shown that *Kanchanara patra phanta* has significant effect in pacifying the symptoms of Hypothyroidism and reduction in the TSH levels. There was marked reduction in the symptoms as well as levels of TSH value, and was well appreciated with the internal administration of *Kanchanara patra phanta* in the form of tea bags for 30 days twice daily (morning and evening). Patient who are accustomed to sedentary lifestyle was observed more with this condition. Among the number of patients observed female being more prone to this condition in between the age group of 20-45 years. *Kanchanara patra phanta* is easy to prepare and palatable to consume, while being effective in managing the condition of Hypothyroidism. Hence, this clinical trial has established the significant potential of formulation *Kanchanara patra phanta* in the management of Hypothyroidism.

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