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EVALUATION OF DEEPANA PACHANA KARMA OF MUSTADI KASAYA GHANAVATI IN HYPOTHYROIDISM : A CLINICAL STUDY

Ayurveda

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ABSTRACT

BACKGROUND- Hypothyroidism is defined as deficient in the thyroidal production. The resistance of the body tissue to the thyroid hormone with respect to metabolic demand results in Hypothyroidism. The hormones of thyroid gland play a critical role in cell differentiation during development and help maintain thermogenic and metabolic homeostasis in the body. Ayurveda has endowed the function of thermogenesis and metabolism in the body to Agni. Symptoms of Hypothyroidism resembles with the Sama Lakshanas and with the Rasa Pradoshaja Vikaras. Shodhana without Ama-Pachana results in further complication. In the present study, Mustadi Gana was selected to evaluate Deepana Pachana Karma in Hypothyroidism as a Rasapradoshaja Vikara. **AIMS & OBJECTIVES-** evaluate Deepana-Pachana Karma of Mustadi Kasaya Ghana-Vati and compare Mustadi Kasaya Ghana-Vati on thyroid functions with standard drug Thyroxine. **METHODOLOGY-** A Randomized Open Controlled Clinical Study. **RESULTS-** Distribution of the study subjects are majorly in between 31-40 years and 41-50 years. The gender wise distribution among 60 study subjects showed 23.3% were male and 76.7% were female. Agninasha, Aruchi Gourava, Angamarda and Tandra were found to be statistically significant in TREATMENT GROUP with $p<0.001$. Weight, BMI and TSH were found to be statistically significant in CONTROL GROUP with $p<0.001$ and <0.005 respectively. **CONCLUSION-** Agni-vaishamya is said to be the primary cause for Rasadushti and Hypothyroidism as the homeostasis of the body is disturbed in both the clinical conditions. Mustadi Kasaya Ghana-vati is an effective Deepana-Pachana Yoga. Mustadi Kasaya Ghana-vati treated group shows significant results for subjective parameters when compared with CONTROL GROUP. Thyroxine treated group shows significant results on thyroid functions when compared with TREATMENT GROUP

KEYWORDS

INTRODUCTION:

Hypothyroidism is defined as deficient in the thyroidal production. The stages of Hypothyroidism are - Subclinical Hypothyroidism, Primary Hypothyroidism and Overt Hypothyroidism. The clinical expression of thyroid hormone deficiency varies considerably between individuals, depending upon the cause, duration and severity of the hypothyroid state. Characteristically, there is a slowing of physical as well as mental activity and many systemic functions. The resistance of the body tissue to the thyroid hormone with respect to metabolic demand results in Hypothyroidism.[1] The global incidence of hypothyroidism is increasing as the thyroid gland easily responds to stimuli like stress and anxiety.[2] According to a projection from various studies on thyroid disorders; In India 42 million people are suffering from thyroid disorders. The commonest endocrine disorder after Diabetes Miletus is Hypothyroidism with prevalence of 5.4% in India[3] with male-female ratio being 1:6[4].

The hormones of thyroid gland play a critical role in cell differentiation during development and help maintain thermogenic and metabolic homeostasis in the body.[5] Standard treatment for hypothyroidism is thyroid hormone replacement. Levothyroxine sodium is the drug of choice in the treatment of hypothyroidism and is prescribed for rest of life, but larger doses may result in complications such as rapid-irregular heartbeat, shortness of breath, tremors etc.[6] Initial dose for replacement therapy begins from 25 to 50mcg/day with gradual increments in dose at interval of 6-8 weeks.

Ayurveda has endowed the function of thermogenesis and metabolism in the body to *Agni*. Proper functioning of *Agni* is responsible for all the metabolic activities in the body. Thereby, *Agnimandya* is said to be the root cause for all the diseases, as it results in the formation of *Ama* affecting the *Rasavaha Srotas*[7] initially. The *Ama Lakshanas* resemble with the *Rasapradoshaja Vikaras*. Symptoms of Hypothyroidism resembles with the *Sama Lakshanas* and with the *Rasa Pradoshaja Vikaras.* Both the conditions fall under the category of *Santarpanotta Vikaras. Kapha Dosha* is said to be the *Asrayee* in *Rasa Dhatu* and thereby the *Rasa Vruddhi Lakshanas* are similar to that of *Kapha Vruddhi Lakshanas*[8]. *Kaphakara Ahara –Vihara* vitiates the *Kapha dosha and Kapha* being a *Pangu dosha* is driven by *Vata dosha* in the *Srotas,* causing *Sroto-avarodha.*

Shodhana without *Ama-Pachana* results in further complication. Therefore the line of treatment revolves around *Srotoshodhana, Pachana, Agnideepana* and *Vatanulomana*[9].

In the present study, *Mustadi Gana* was selected to evaluate *Deepana Pachana Karma* in Hypothyroidism as a *Rasapradoshaja Vikara.* It is said to be *Sleshma Nishudana*[10]*, Mala-Pachana* having its indication in *Kaphaja Stanya Dushti* and *Kaphaja yonivyapat*[11]*;* as *Stanya* and *Artava* are the *Upadhatus* of *Rasadhatu* the above mentioned *Gana* was selected for the study to evaluate its *Deepana Pachana Karma* in Hypothyroidism as *Rasapradoshaja Vikara.*

OBJECTIVES:

- To evaluate *Deepana-Pachana Karma* of *Mustadi Kasaya Ghana-Vati.*
- To compare *Mustadi Kasaya Ghana-Vati* on thyroid functions with standard drug Thyroxine.

METHODOLOGY: The data for the present study were collected in following phases-

a) Pharmacognostical Study
b) Physico-chemical Study
c) Pharmaceutical Study
d) Clinical Study

a) Pharmacognostical Study:

Macroscopic evaluation: The macroscopic characters of the *Mustadi Kasaya Churna* were observed for colour, taste and odour.

b) Physico-Chemical Study:

The following physico-chemical tests were carried out for *Mustadi Kasaya Churna* as per the standard protocol.

- Determination of Foreign Matter
- Determination of Moisture Content (Loss on drying)
- Determination of Ash Value
- Determination of Alcohol and Water Soluble Extractive Value
- Determination of Ph Value

c) Pharmaceutical Study:

The following pharmaceutical tests were carried out for *Mustadi Kasaya Ghanavati* as per the standard protocol.

- Hardness
- Uniformity of weight
- Uniformity of diameter
- Friability Test

d) Clinical Study:
60 subjects were selected for the study and were randomly allocated to two groups containing 30 subjects in each. Group A was treated with standard drug Thyroxine and Group B was treated with *Mustadi Kasaya Ghana-Vati* during study period. Subjects for Group A (Control) were selected based on the inclusion criteria from Darla's Health Care. Subjects for Group B (Treated) were selected from IPD and OPD of JSS Ayurveda Hospital- Mysuru, Medical camps, and other referrals.

All the 60 patients suffering from Hypothyroidism were selected for the study after fulfilling inclusion and exclusion criteria mentioned below.

Inclusion criteria:
- Subjects having *Lakshanas* of *Rasapradoshaja vikara* (Hypothyroidism) with TSH ranging from 5.5 uIU/ml to 50uIU/ml with or without association of T_3 & T_4.
- Patients diagnosed as Hypothyroidism and already on medications, fulfilling the diagnostic criteria.
- Subjects of age group between 18 to 60 years.
- Subjects of either gender.

Exclusion criteria:
- Other types of Hypothyroidism such as Secondary Hypothyroidism, Hashimoto's disease, Cretinism.
- Pregnant and lactating women.

Diagnostic criteria: Based on subjective and objective criteria.

Groups	Subjects	Drug	Anupana	Intervention	Total Duration
A	30	Thyroxine	---	60 days	60 days
B	30	Mustadi Ghana-Vati	Ushnajala	60 days	60 days

Assessment Criteria:
Subjective Parameters:
1) Agninasha
2) Aruchi
3) Angamarda
4) Gourava
5) Tandra

Objective Parameters:
1) Thyroid Function Tests: T_3, T_4, TSH
2) Body Mass Index.
3) Body weight.

Ethical clearance was obtained from Institutional Ethical Committee (IEC). Informed consent was prepared in Kannada and English languages. Details of the study and all the other information pertaining to it was informed to the patient / patient's attendant.

Preparation of Trial Drug: *Mustadi Kasaya Ghanavatis* were prepared at NKCA PHARMACY, Mysuru.

1. Preparation of Mustadi Gana Churna:
a) Sukshma Churna – The raw materials were procured at NKCA PHARMACY, Mysuru. They were taken in a quantity of 400 grams each and were pulverized into fine powder. A yield of about 5kgs was obtained.
b) Kwatha Churna – The same raw materials were taken in quantity of 150 grams each and were pulverized into coarse powder. An yield of about 1.7Kgs was obtained.

2. Preparation of Mustadi Gana Kasaya: *Kwatha Churna* of *Mustadi Gana Dravyas* were taken and mixed with 16 parts of water (about 30 litres approximately). It is then boiled on low flame and reduced to 1/2. After it is cooled, the *Kasaya* is filtered. An yield of about 15 litres was obtained.

3. Preparation of Mustadi Gana Kalka: The prepared *Kasaya* and *Sukshma Churna* of *Mustadi Gana* were taken together in a wet grinder and grinded till the mixture turned into a *Kalka* (bolus). The *Kalka* was then dried in shade for about 24 hours. Further it was taken in Mass Mixer Machine for proper mixing of the mass, till a proper consistency was obtained.

4. Preparation of Mustadi Gana Varti: The *Kalka* was then inserted into *Varti* Making Machine. The *Vartis* were collected in a clean tray.

5. Preparation of Mustadi Ghanavati: The *Vartis* were then put into Automatic Pill Cutting Machine and round *Vatis* were collected in clean and dry container. The *Vatis* were then dried in shade for about 2-3 days.

6. Coating of Mustadi Ghanavati: The dried *Mustadi Ghanavatis* were poured into the rotator and required quantity of *Mustadi Kasaya* was sprinkled over the *Vatis*. After the completion of coating, the *Vatis* were collected in clean and dry tray and were kept for drying in shade for about 2-3 days.

Statistical Methods:
In the current study, the data obtained was entered in MS-Excel 2007 and analysed using IBM SPSS software version 21. It was found that the data was not from the normal distribution as determined by Kolmogorov Smirnoff normality test. Hence non parametric tests of significance i.e., Wilcoxon Signed Rank Test and Mann-Whitney U tests were applied to check the statistical significant differences between the means of subjective parameters of two groups and are represented as tables and graphs as relevant.

In the current study, parametric tests of significance i.e., Paired t-test and Un-paired t-tests were applied to check the statistical significant differences between the means of objective parameters in the intra and intergroups respectively and are represented as tables and graphs.

OBSERVATIONS:

Table No 1: Comparision of Sama-Dosha Lakshanas with Rasapradoshaja Lakshanas

Sama Dosha Lakshanas	Rasapradoshaja Lakshanas
1. Gourava, Alasya, Klama (Sama Kapha)	Gourava, Alasya, Klama and Balabhramsha
2. Aavil-Tantula-Styana, Durgandhi Kapha, Aruchi (Sama Kapha).	Asraddha-Aruchi, Arasajnata, Asya-vairasya
3. Nishtiva (Sama Kapha)	Praseka.
4. Agnisadana, Apakti (Sama Kapha).	Agnisadana
1. Vedana, Nistoda (Sama Vata)	Angamarda
2. Vibandha, Anila Mudhata, Malasanga (Sama Vata)	Sakrt graham
3. Shopha (Sama Vata)	Pandutwam

Table No 2: Clinical Presentations of Hypothyroidism and Rasapradoshaja Lakshanas

1 Fatigue, Lethargy, Loss of energy	i. Gouravam ii. Alasya Klama, Balabhram
2. Weight Gain	i. Sthoulya
3. Decreased Appetite	i..Asraddha-Aruchi, Arasajnata, Asya-vairasya
4. Anorexia	i. Praseka, Agnisadana
5. Cold Intolerance, Hypothermia	i. Shaitya
6. Dry Skin, Scaly Skin,	i. Roukshya
7. Pallor	i. Pandutwam
8. Hair fall, Coarse Brittle Straw like Hair	i. Ayathakala Palitya
9. Extreme Somnolence	i. Tandra ii. Ati-nidrata
10. Muscle pain, Weakness in extremities, Joint pain	i. Angamarda
11. Sluggishness of Muscle	i. Slathangatwam
12. Constipation	i. Sakrt graham
13. Impaired Fertility	i. Klaibya
14. Hoarseness of Voice	i. Kaphaja Swarasada
15. Decreased Hearing	i. Shabda-asahishnutam
16. Bradycardia	i. Hrut-Peeda, Hrut-Kampa

Table No 3: Organoleptic Tests Of *Mustadi Kasaya Ghanavati*

TRIAL DRUG	COLOUR	ODOUR	TASTE
Mustadi Kasaya Ghanavati	Dark Brown	Characteristic Odour	Bitter

Table No 4: Physico-chemical Tests Of *Mustadi Kasaya Churna*

SL NO.	PHYSICO-CHEMICAL TESTS	RESULTS
1.	Determination of Foreign Matter	Absent

2.	Determination of Moisture Content	9.94%
3.	Determination of Total Ash	5.68%
4.	Determination of Acid Insoluble Ash	0.79%
5.	Determination of Water Soluble Ash	4.65%
6.	Determination of Alcohol Soluble Extractive	2.82%
7.	Determination of Water Soluble Extractive	8.84%
8.	Determination of pH of 10% Solution	4.28

Table No 5: Pharmaceutical Study Of *Mustadi Kasaya Ghanavati*

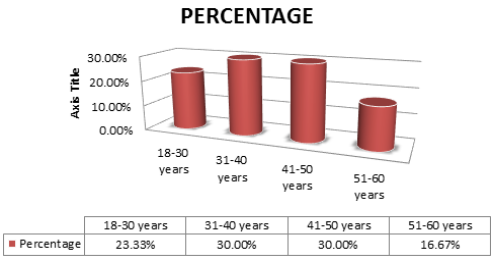
SERIAL NO.	PHARMACEUTICAL TESTS	RESULTS
1.	Hardness Test	10.56 Kg/m2
2.	Uniformity of Weight	0.19745g
3.	Uniformity of Diameter (Thickness)	7.104mm
4.	Friability Test	1.07%

Table No 6: Age wise distribution of study subjects

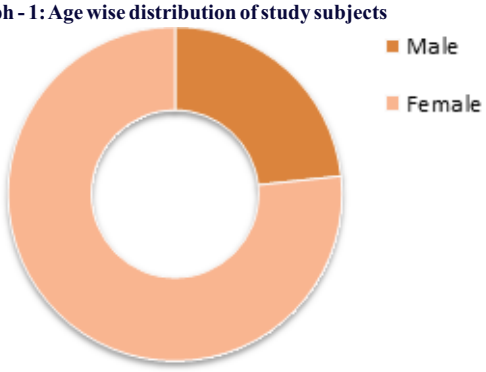
Age Range	Frequency	Percentage
18-30 years	14	23.33%
31-40 years	18	30.00%
41-50 years	18	30.00%
51-60 years	10	16.67%
Total	60	100.00%

Table No 7: Gender wise distribution of study subjects

Gender	Frequency	Percentage
Male	14	23.30%
Female	46	76.70%
Total	60	100.00%



Graph - 1: Age wise distribution of study subjects



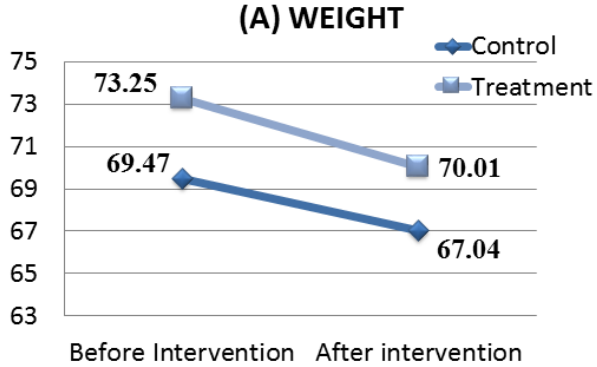
Graph - 2: Gender wise distribution of study subjects

Table No 8(A): Intergroup Comparison of the mean values of objective parameters before and after intervention among the patients of Control and Treatment groups.

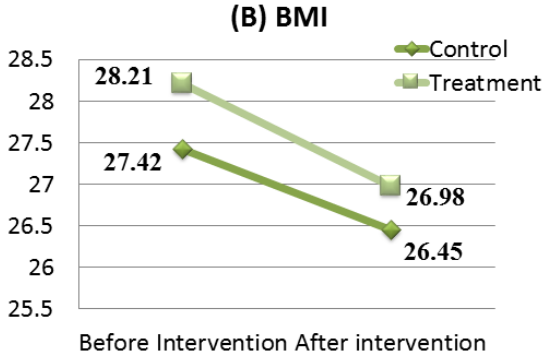
Test Variables	Phase of Intervention	Group		Mean Difference ± SE	Z score	P value
		Control (Mean ± SD)	Treatment (Mean ± SD)			
Agninasha	Before Intervention	0.67 ± 0.47	0.70 ± 0.46	-0.03 ± 0.12	-0.275	0.783
	After Intervention	0.17 ± 0.37	0.00 ± 0.00	0.17 ± 0.69	-2.316	0.021*
Aruchi	Before Intervention	0.67 ± 0.47	0.67 ± 0.48	0.00 ± 0.12	0.000	1.000
	After Intervention	0.17 ± 0.37	0.00 ± 0.00	0.17 ± 0.69	-2.316	0.021*
Angamarda	Before Intervention	0.50 ± 0.50	0.70 ± 0.48	-0.20 ± 0.12	-1.568	0.117
	After Intervention	0.20 ± 0.40	0.33 ± 0.48	-0.13 ± 0.12	-1.158	0.247
Gourava	Before Intervention	0.67 ± 0.47	0.90 ± 0.30	-0.23 ± 0.10	-2.17	0.030
	After Intervention	0.30 ± 0.46	0.10 ± 0.30	0.20 ± 0.10	-1.920	0.055
Tandra	Before Intervention	0.47 ± 0.50	0.53 ± 0.50	-0.06 ± 0.13	-0.512	0.609
	After Intervention	0.17 ± 0.37	0.03 ± 0.18	0.13 ± 0.07	-1.707	0.088

Table No 8(B): Intergroup Comparison of the mean values of subjective parameters before and after intervention among the patients of Control and Treatment groups.

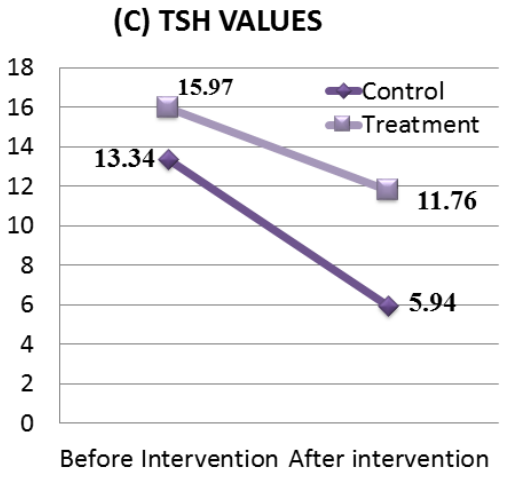
Test Variables	Phase of Intervention	Group		Mean Difference ± SE	Unpaired t test score	P value
		Control (Mean ± SD)	Treatment (Mean ± SD)			
Weight	Before Intervention	69.47 ± 13.34	73.25 ± 13.36	-3.78 ± 3.44	-1.099	0.325
	After Intervention	67.04 ± 12.52	70.01 ± 12.01	-2.97 ± 3.16	-0.940	0.351
BMI	Before Intervention	27.42 ± 5.20	28.21 ± 3.35	-0.79 ± 1.12	-0.702	0.486
	After Intervention	26.45 ± 4.79	26.98 ± 3.10	-0.53 ± 1.04	-0.508	0.614
TSH Levels	Before Intervention	13.34 ± 10.51	15.97 ± 12.21	-2.63 ± 2.94	-0.896	0.317
	After Intervention	5.94 ± 5.23	11.76 ± 9.50	-5.82 ± 1.98	-3.526	0.005*



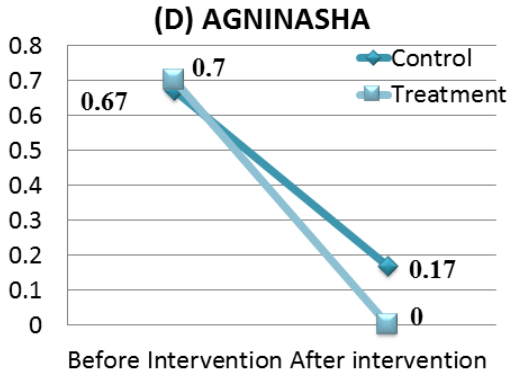
Graph 3: Mean weights of study participants from the control and treatment groups before and after intervention



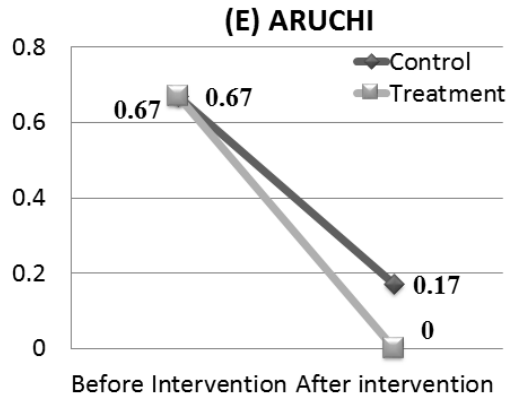
Graph 4: Mean BMI values of study participants from the control and treatment groups before and after intervention



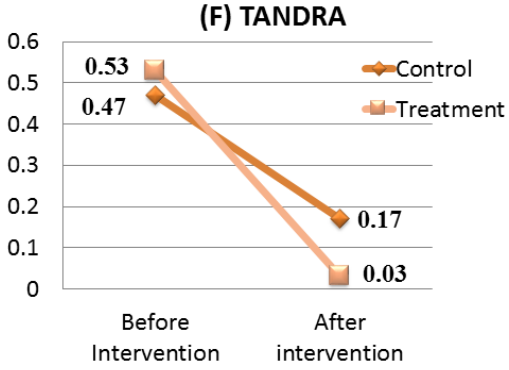
Graph 5: Mean TSH values of study participants from the control and treatment groups before and after intervention



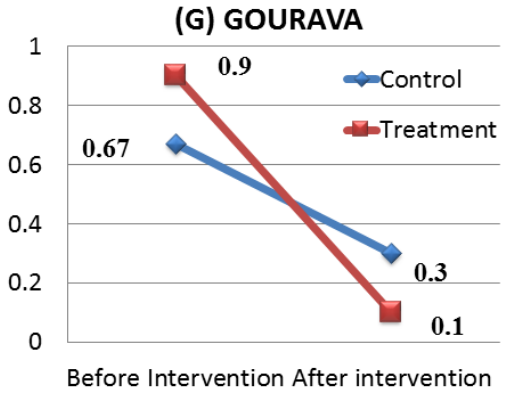
Graph 6: Mean of Agninasha grades study participants from the control and treatment groups before and after intervention



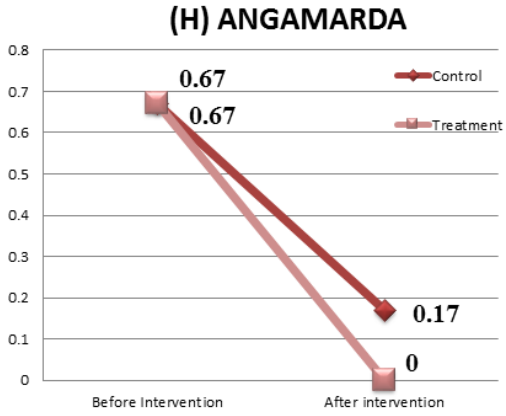
Graph 7: Mean Aruchi grades of study participants from the control and treatment groups before and after intervention



Graph 8: Mean Tandra grades of study participants from the control and treatment groups before and after intervention



Graph 9: Mean Tandra grades of study participants from the control and treatment groups before and after intervention



Graph 10: Mean Angamarda grades of study participants from the control and treatment groups before and after intervention

RESULTS:

Distribution of the study subjects are majorly in between 31-40 years and 41-50 years. This indicates the disease is more prevalent in the age group between 31-40 years and 41-50 years. The gender wise distribution among 60 study subjects showed 23.3% were male and 76.7% were female. All the subjective parameters showed statistically significant results within the groups. When compared between the groups, Agninasha, Aruchi *Gourava, Angamarda* and *Tandra* were found to be statistically significant in TREATMENT GROUP with $p<0.001$. Weight and BMI were found to be statistically significant within the Groups of A&B. When compared between the groups, it was found to be statistically significant in CONTROL with $p<0.001$. The TSH values were found to be statistically significant within the Groups. When compared between the groups the TSH values are found to be highly significant in the CONTROL with $p<0.005$.

DISCUSSION:

Autoimmune diseases have become one of the most common diseases increasing at ranges between 3% and 9% year on year[12] due to the unhealthy and sedentary lifestyle which is causing an imbalance in immune response. Women are less susceptible to infectious diseases than men, but are more often prone to autoimmune diseases. This higher prevalence is partly attributable to the X chromosome, which has many genes relating to the immune system, as a result there is a greater tendency to develop autoimmunity.[13] 80% of individuals with autoimmune diseases are women.[14]

Hypothyroidism is defined as deficient in the thyroidal production. It is a graded phenomenon, ranging from very mild cases to very severe life threatening cases of myxedema coma in which biochemical abnormalities are present but the individual hardly notices symptoms and signs of thyroid hormone deficiency. The clinical expression of thyroid hormone deficiency varies considerably between individuals, depending upon the cause, duration and severity of the hypothyroid state. Characteristically, there is a slowing of physical as well as mental activity and many systemic functions.[15]

Standard treatment for hypothyroidism is thyroid hormone

replacement.

Levothyroxine is prescribed as the sodium salt in order to enhance its absorption. Absorption is more complete and less eractic if the daily dose is taken in the fasting state. In patients over the age of 70, levothyroxine requirements are reduced to about 25%, with relative decrease in body mass with age.[16]

The oral administration of L-triiodothyronine sodium is more readily absorbed than T_4. Its peak levels are observed within 2 – 4 hours. Preparations of L-T_3 are not recommended for long term replacement therapy in hypothyroidism. Pharmacodynamic equivalence of levothyroxine and liothyronine is achieved at a dose ratio of about 3:1.[17]

The rapidity with which normal thyroid hormone levels should be restored depends on a number of factors, including the age of patient, the duration and severity of hypothyroidism, and the presence or absence of other disorders, particularly those of the cardiovascular system.

A TSH value of <0.1mU/l has been identified as a risk factor for the development of atrial fibrillation.[18] Long term levothyroxine therapy in TSH-suppressive doses may cause left ventricular hypertrophy and increases the risk of ischaemic heart disease in patients under the age of 65 years.[19] TSH suppressive doses of levothyroxine have been associated with bone loss due to reduced bone-mineral density in hypothyroid patients, specially in post menopausal women.[20] Patients with low TSH did not have an increased risk of any of these outcomes. Thus it may be safe for patients treated with T_4 have a low but not suppressed serum TSH.

Increased dose adjustment is done in decreased intestinal absorption of T_4, reduced gastric acid secretion, mal-absorption, bowel syndrome, increase in weight gain and in increased metabolic clearance of T_4.

Decreased dose adjustment is done in weight loss and in decreased metabolic clearance of T_4 specially in old age.

The food that is ingested is mainly digested by the *Jatharagni* as it transforms the food into its essence, required for the nourishment of the body and thereby regulates the metabolic homeostasis among the *Dosha-Dhatu-Mala* in the body. This infers that *Jatharagni* acts at the level of stimulation of the TSH from the anterior pituitary which maintains the equilibrium of thyroid hormones. Further, at the cellular differentiation during development, *Bhutagni* is the one which gets activated and nourishes the respective *Mahabhuta* present in the body. Here *Pancha-Mahabhutas* acts as the functional units of the body for its sustenance as that of a cell. The nutrients reach the blood stream after getting metabolized for the regulation of chemical processes. This infers the role of *Dhatvagni* in nourishing the organs and tissues of the body. The essence that is completely metabolized circulates in its respective *Srotases* for the formation and nourishment of *Dhatus* by the virtue of *Dhatvagni.* The *Rasa dhatu* formed from *Ahara rasa* regulates the hormonal secretion by the virtue of proper functioning of *Agni*.

Thus Agni plays a critical role in regulating the metabolic homeostasis in the body as that of the thyroid hormones.

Due to *Ajeerna-ashana, Adhyashana, Vishamashana* by *Guru-Shita, Snigdha Ahara,* and *Ati Chintana*; *Agni* gets impaired resulting in the formation of *Ama.*

Thereafter the metabolism is altered at the level of cellular differentiation which leads to an imbalance in the thyroidal secretion of T_4 initially. This is compensated with the slight elevation in the serum TSH. The condition is asymptomatic and is diagnosed with Sub-clinical Hypothyroidism. As the patho-physiology continues, metabolism is impaired causing *Agnimandya* and subsequently *Rasa Dushti*. The symptoms such as *Agninasha, Aruchi, Gourava* etc are exhibited. As the disease pathogenesis further progresses it impairs the successive *Dhatu's* qualitatively and quantitatively. Similarly, the decline in the thyroidal secretion of T_4, is again compensated with elevated TSH values. As a result there is an inadequacy in the production of thyroid hormone and this condition is diagnosed as Primary Hypothyroidism.

The genetic cause can be considered as *Matruja* and *Rasaja bhava janya roga* because of strong familial presentation and autosomal dominant inheritance respectively.

Symptoms of Hypothyroidism resembles with the *Sama Lakshanas* and with the *Rasapradoshaja Vikaras.* Both the conditions fall under the category of *Santarpanotta Vikaras.*

Precisely *Kapha* has more affinity towards the *Rasa Dhatu. Rasa Vruddhi Lakshanas* are similar to that of *Kapha Vruddhi Lakshanas.* As explained before in the etio-pathology of the disease, *Kaphakara Ahara –Vihara* vitiates the *Kapha dosha and Kapha* being a *Pangu dosha* is driven by *Vata dosha* in the *Srotas,* causing *Sroto-avarodha.*

The imbalance in the hormonal secretion is due to *Agni-vaishamya* in the *Mahasrotas* which results in the formation of *Ama* causing *Sanga* along with *Vimargagamana* type of *Srotodushti.*

Samprapti Ghataka

Dosha : *Kapha Pradhana Dosha, Vata Anubandha Dosha*
Dushya : *Rasa*
Agni : *Jatharagni-Mandya* leading to *Rasa Dhatwagni Mandya*
Srotas : *Rasavaha Srotas*
Srotodushti : *Sanga*
Udbhava Sthana : *Amashaya*
Rogamarga : *Abhyantara*

In the present study, *Mustadi Gana* was selected to evaluate *Deepana Pachana Karma* in Hypothyroidism as a *Rasapradoshaja Vikara.* The *Dravyas* mentioned in *Mustadi Gana* are *Musta, Vacha, Chitraka, Haridra, Daru haridra, Katuki, Kiratatikta, Bhallataka, Patha, Triphala, Ativisha, Kushta* and *Ela.* Out of 15 *Dravyas,* 8 of them posses *Katu-Tikta -Kasaya Rasa* and *Ushna Virya*; 4 of them posses *Tikta-Katu Rasa* and *Shita Virya*; 2 of them posses *Kasaya Rasa* and *Ushna Virya*; 1 having *Amla Rasa* and *Shita Virya.* 11 *Dravyas* posses *Katu Vipaka* and remaining 4 *Dravyas posses Madhura Vipaka*.

The therapeutic action of the *Gana* is due to synergism of all the dravyas with the predominance of *Katu-Tikta Rasa*, *Ushna Virya*, *Katu Vipaka* and *Laghu-Ruksha-Tikshna Guna.*

In *Mustadi Gana* we come across both *Samana Pratyarbdha Dravyas* as well as *Vichitra Pratyarbdha Dravyas,* but due to the presence of more *Samana Pratyarbdha Dravyas* (9 *Dravyas* out of 15) in the *Gana,* the expected therapeutic action could be assessed based on their respective *Rasapanchakas;* where-in 7*Dravyas* posses *Deepana Pachana Karma,* 3 *Dravyas* posses *Lekhana Karma*, 3 *Dravyas* posses *Bhedana Karma* and 2 *Dravyas* posses *Anulomana Karma.*

Herbal drugs can be preserved for longer duration in different dosage forms like *Churna*, *Leha* etc. These formulations have less water content and reduced water activity resists the growth of micro-organisms. Liquid dosage forms cannot be preserved for longer duration because of growth of micro-organisms. *Kwatha* is the most common formulation used in practice and is easily prone to microbial attack. Due to the addition of preservatives the shelf life of *Kwatha* is increased. The alternative method to preserve *Kwatha,* is to convert them into different dosage forms like *Ghana-Vati.*[21] In the current study *Kasaya Ghanavati's* of *Mustadi Gana* were prepared with similar perspective. *Mustadi Gana Kasaya* posses *Tikta rasa* predominantly which becomes unpalatable to consume. Thus *Kasaya Ghana-Vati* was chosen as the *Dravya Kalpana* in the study.

Randomized controlled trials are the most reliable method available for testing new treatments. Therefore the current study was designed with alternate type of randomization for the trials. In the current study Group A was treated with Standard Control drug thyroxine for 60 days and Group B was treated with *Mustadi Kasaya Ghanavati* for the same duration. Lab investigations were done before and after the completion of intervention for comparison within the group and between the groups.

Among 60 subjects 10 were diagnosed with PCOD and 10 were diagnosed with hair fall as an associated complaint.

PCOD: Irregular menstrual periods are a hallmark feature of PCOD and occur as a result of increased androgen levels, causing immature ovarian follicles in the form of cysts within the ovary and thereby preventing regular monthly ovulation.[22]

In hypothyroidism, there is a rise in the level of prolactin hormone which prevents ovulation, leading to polycystic ovaries. [23]

Patients diagnosed with PCOD and hypothyroidism had a symptomatic relief in the treated group. As *Mustadi gana* is indicated in *Kaphaja Yonivyapat.*

Hairfall: Severe and prolonged hypothyroidism cause diffuse loss of hair over entire scalp. It is apparent after several months of the onset of hypothyroidism. Thus it is unusual at sub-clinical level. Re-growth is usual and successful with thyroxine medications; though it takes several months for regeneration of hair with a change in its texture and colour.[24]

The subjective parameters for the present study were *Agninasha*, *Aruchi, Gourava, Angamarda* and *Tandra.* Among these all the subjective parameters showed statistically significant results within the groups. When compared between the groups, Agninasha, Aruchi *Gourava, Angamarda* and *Tandra* were found to be statistically significant in TREATMENT GROUP with $p<0.001$. This shows the therapeutic effect of the trial drug as an efficient *Deepana-Pachana Dravya* along with *Srotoshodhana, Lekhana* and *Shoshana Karma's.*

The objective parameters for the present study were Weight, BMI and TSH values. Among these Weight and BMI were found to be statistically significant within the Groups of A&B. When compared between the groups, it was found to be statistically significant in CONTROL with $p<0.001$, as *Lekhana* and *Ama-Pachana Karma* of the trial drug is not sufficient to reverse the symptom and it further requires *Shodhana.*

The TSH values were found to be statistically significant within the Groups. When compared between the groups the TSH values are found to be highly significant in the CONTROL with $p<0.005$, as thyroxine being the standard drug of choice for hormone replacement in hypothyroidism.

CONCLUSION:

Agni-vaishamya is said to be the primary cause for *Rasadushti* and Hypothyroidism as the homeostasis of the body is disturbed in both the clinical conditions. Thus, *Ama-pachana* and *Agni-deepana* have a vital role in the *Samprapti Vighatana* of hypothyroidism. *Mustadi Kasaya Ghana-vati* is an effective *Deepana-Pachana Yoga. Mustadi Kasaya Ghana-vati* treated group shows significant results for subjective parameters when compared with CONTROL GROUP. Thyroxine treated group shows significant results on thyroid functions when compared with TREATMENT GROUP. Withdrawal of Thyroxine in the patients of hypothyroidism with controlled TSH levels, leads to exacerbation of symptoms. Therapeutic efficacy of *Mustadi Kasaya Ghana-vati* proves to be effective in preventing the progress of the disease, followed by *Shodhana.*

Figures of Drug Preparation

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