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PHARMACOLOGICAL & CLINICAL STUDY OF BRAHMI, GANDIRA & PIPPALI ON HYPOTHYROIDISM

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Abstract: Hypothyroidism is a disease, which has less secretion of thyroid hormone. It is characterized by a broad clinical spectrum ranging from an asymptomatic or subclinical condition with normal levels of thyroxin (T4) and triiodothyronine (T3) and elevated levels of serum TSH to an overt state of myxedema, end-organ effects and multi-system failure.

Aims and Objectives: To study pharmacological aspect of Bacopamonnieri, Coleus forskohlii, Piper longum. To review the literature of Hypothyroidism as described in ayurvedic text and modern texts. Pharmacological & clinical study of BGP-60 (hypothetical formulation), mixture of Bacopamonnieri, Coleus forskohlii, Piper longum,

Materials and Methods: The whole study will be carried out under 2 major phases-(i). Pharmacognostical & Clinical Study. (ii). Evaluation of Dosha Shamak properties of Formulation and as well as individual drug. Clinically diagnosed patient of 'hypothyroidism' will be divided randomly in 4 groups. 10 patients will be included in each group. Group A-10 patient of hypothyroidism will be treated by 500 mg Brahmi powder, 2 capsule. 2 times a day with lukewarm water for 60 days. Group B-10 patient of hypothyroidism will be treated by 3 g Gandeer powder, 2 times a day with lukewarm water for 60 days. Group C-10 patient of hypothyroidism will be treated by 250 mg Pippali powder, 2 capsules 2 times a day with lukewarm water for 60 days. Group D-10 patient of hypothyroidism will be treated by 3250 mg powder BGP-60 2 times a day with lukewarm water for 60 days.

Results: Statistically significant result was observed in All Groups.

Conclusion: Therapy in the form of administration of Brahmi, Gandeer, Pippali And BGP-60 separately or in combination is a safe and effective in the management of Hypothyroidism

Keywords: Hypothyroidism Bacopamonnierilinn., Coleus forskohliilinn, Piper longumlinn.

Introduction: With the changing life style of 21st century hypothyroidism is considered as one of the most common diseases. It is the most common endocrinological disorder that occurs when the thyroid gland doesn't make enough thyroid hormone to meet the body's needs. It is a clinical syndrome resulting from deficiency of thyroid hormones due to their insufficient synthesis which in turn results in a generalized slowing down of metabolic processes. It is characterized by a broad clinical spectrum ranging from an asymptomatic or sub-clinical condition with normal levels of thyroxin (T4) and triiodothyronine (T3) and elevated levels of serum TSH to an overt state of myxedema, end-organ effects and multi-system failure. It is based almost exclusively upon measuring the amount

of thyroid hormone in the blood, usually the levels of TSH

According to Ayurveda, it is Saman Vayu Dushti.

समानेनावधूतोऽग्निरुदर्यः पवनोद्वहः कालेभुक्तं समं
सम्यक् पचत्यायुर्विवृद्धये॥ (च.चि.15/7)

Saman Vayu stimulates various digestive glands to secrete various digestive enzyme (Pitta), which digest the food. In Ayurveda it is abnormality of Jatharagni and Dhatwagni along with abnormality of Kapha and Vata Dosha as well as Rasavaha, Raktavaha, Medovaha, Shukravaha and Manovaha Srotas Dushti. (Ch.Su.28/8-19) Thus, the treatment line involves Deepana, Pachana, Srotoshodhana and Kapha Vata Shamana. In this study these factors will be addressed during Ayurvedic management of hypothyroidism. Saman Vayu stimulates various digestive glands to secrete various

digestive enzymes (*Pitta*) that digest the food.

Involvement of *Agni* in Hypothyroidism

आयुर्वर्ण बलं स्वास्थ्यमुत्साहोपचयौ प्रभा ओजस्ते

जोऽग्नयः प्राणाश्चोक्ता देहाग्निहेतुकाः^[1]

Normalcy of all mechanisms of the body is totally dependent upon the normal functioning of *Agni*. According to allopathic systems, metabolic activity of the body is controlled by thyroid hormone secretion and if we take a glance towards *Ayurveda*, we could see that metabolic processes of the body are under the control of *Jatharagni*, *Bhutagni* and *Dhatvagni*, as quoted by *Charaka*,

Some Clinical Conditions Correlating with Hypothyroidism:

Acharya Charaka described a clinical condition in *Dosha Vikalpa Kalpana* presenting as *Pitta Kshaya with Kapha and Vata Vriddhi*^[2] *Kaphavritta Vata*^[3] *Kaphavritta Udana*^[4], *Kaphavritta Samana*^[5], *Kaphavritta Vyana*^[6] *Kaphaja Pandu*^[7] *Bahudoshavastha*^[8] conditions show similarity to the clinical presentation of hypothyroidism to some extent.

Need for the Study: Thyroid disorders are the most common disorders of the endocrine glands. It is estimated that about 42 million people suffer from thyroid disorders in India. The prevalence of hypothyroidism in Udaipur Rajasthan is 9.33%. Women are 6 times more prone than men. Hypothyroidism is one of the most common functional disorders of thyroid gland. The incidence of Hypothyroidism is increasing day by day, and there is increasing demand for treating the disease through the *Ayurvedic* system of medicine, as it is completely natural and safe. Hypothyroidism can be treated effectively if we understand the disease and select effective drugs.

| S.N. | Groups | Posology | Duration | Anupana | Kala | Follow Up |
|------|--------------|-------------------|----------|----------------|--------------|---------------|
| 1. | B.M. Capsule | 2gm(500mgx2 B.D.) | 60 Days | Lukewarm water | Before meal. | Every 30 days |
| 2. | C.F. Powder | 6gm(3gm x 2 BD.) | 60 Days | Lukewarm water | Before meal. | Every 30 days |
| 3. | P.L. Capsule | 1gm(500mgx1 B.D.) | 60 Days | Lukewarm water | Before meal. | Every 30 days |
| 4. | BGP-60 | 6gm(3gm x 2 BD.) | 60 Days | Lukewarm water | Before meal. | Every 30 days |

Method of Medicine Preparation

| S. No | Plant | Latin Name | Composition |
|-------|-----------------|-------------------|---------------------|
| 1. | Brahmi Panchang | Bacopamonnieri | 2500 mg powder |
| 2. | Gandira Root | Coleus forskohlii | 500 mg powder |
| 3. | Pippali Fruit | Piper longum | 250 mg powder |
| | BGP-60 | Mixed formulation | 3250 mg powder B.D. |

Criteria for Assessment: All patients were assessed with the help of signs and symptoms of Hypothyroidism.

Subjective Parameters: Improvement in the signs and symptoms in the patients of hypothyroidism according to Hutchisons, Harrison's.

Materials and Methods: The whole study will be carried out under 2 major phases-

1. Pharmacognostical & Clinical Study.
2. Evaluation of Dosha Shamak properties of Formulation and as well as individual drug.

Selection of Cases: 10 Patients each group selected, who were fulfilling the criteria, attended the OPD/IPD of MMM Govt. Ayurvedic College Hospital Udaipur, Rajasthan and other palaces were selected for the present study irrespective of age, sex, religion, etc.

A. Inclusion Criteria

- Patient's under the age group 20-60 years.
- Male and female both were included.
- Patients who are diagnosed as Hypothyroidism.
- Serum T₃, T₄ and TSH levels which indicated Hypothyroidism.
- Patients who were ready to switch over the *Ayurvedic* medicine and signed the informed consent form.

B. Exclusion Criteria

- Patients who had under gone any type of thyroid surgery.
- Patients, who were suffering from systemic diseases like cardiac problems, diabetes, carcinomas etc.
- Patients, who were suffering from congenital hypothyroidism and secondary hypothyroidism.
- Pregnant women, children hyperthyroidism, neoplasia, toxic goiter were excluded.

C. Drug and Posology: Drug: *Brahmi*, *Gandira*, *Pippali*, *Gandiradi Yoga*/ BGP-60

Objective Parameters

- Body weight
- Serum T₃
- Serum T₄
- TSH (Thyroid Stimulating Hormone)

Investigations

- Blood : Hb%^{gm}
- Thyroid Function Test : SerumT₃, SerumT₄,

Serum TSH (Thyroid Stimulating Hormone)

- Other necessary investigations were carried out.

Administration of Drugs: Clinically diagnosed and registered patient of 'hypothyroidism' were divided randomly in 4 groups. 10 patients were included in each group.

Group A: 10 patient of hypothyroidism were treated by 500 mg Brahmi powder, 2 capsule. 2 times a day with lukewarm water for 60 days.

Group B: 10 patient of hypothyroidism were treated by 3 g Gandeer powder, 2 times a day with lukewarm water for 60 days.

Group C: 10 patient of hypothyroidism were treated by 250 mg Pippali powder, 2 capsules 2 times a day with lukewarm water for 60 days.

Group D: 10 patient of hypothyroidism will be treated by 3250 mg powder Gandiradi Yoga/BGP-60 2 times a day with lukewarm water for 60 days.

Individual group (A, B, C) Study is subject to matter of time and availability of patients.

Assessment of Therapy: The assessment was done in the following manner. There clinical features and Sr.TSH, Sr.T3 & Sr.T4 levels were assessed before starting treatment, after completion of *Shamana* treatment. The other investigations like Hb%, TLC, DLC, ESR and Serum Cholesterol, Serum Triglycerides etc. were also compared. Following score pattern was adopted for sign and symptoms (i.e. Chief and associated Complaints).

| Grade | Complaint |
|-------|--------------------------------|
| 0 | No complaint |
| 1 | Presence of mild complaint |
| 2 | Presence of moderate complaint |
| 3 | Presence of severe complaint |
| 4 | Agonizing |

Criteria for Overall Effect of Therapy

| | | |
|-----------|---------|------|
| Nil | 0% | - |
| Mild | 1-25% | + |
| Moderate | 26-50% | ++ |
| Severe | 51-75% | +++ |
| Agonizing | 76-100% | ++++ |

In this study total 50 patients of Hypothyroidism were registered. Patients were randomly divided under four groups 'viz. group A, group B and group C. and group D maximum (37.5%) patients were belonging to the age group of 31-40 years followed by 35.0% patients were belonging to 51-60 years age group. 85 % were females, and 97.5% patients were married. 35.56% patients were educated up to higher secondary. 40% patients were housewives, 72.5% patients were belonging to upper middle class.

Maximum i.e. 90% of patients was taking raw vegetables. 85% patients have doing *Viruddhashana*. . The excessive usage of milk and curd were found to be the etiological factor in 82.5% & 80% of the patients respectively. *Vishamashana* was doing by 80% of the patients followed by *Ahitashana* was doing by 75% of the patients and 72.5% of the patients were taking *Vishtambhi Ahara*. 70% patients were shown *Medyanama Atisevana*. The family history of Hypothyroidism was present in 27.5 % of the patients. 82.5% patients were having positive drug history.

Dashvidha Pariksha: Maximum, 60% of the patients were of *Kapha-Vata Prakrti*, 77.5% of the patients were of *Rajas Prakrti*, 77.5% of

patients had *Madhyama Sara*, *Madhyama Samhanana* was found in 95% patients, 57.5% of patients had *Samapraman*, 95% of patients were having *sarvarasasatmya*. 50% of patients were of *Madhyama Sattva* 50% patients were having *Madhyama Abhyavaharana Shakti* 55% patients have shown *Madhyama Jarana Shakti*, 50% patients were having *Madhyama Vyayama* 42.5% patients were having *Samagni* followed by 22.5% patients of *Tikshnagni* 20% patients were having *Mandagni* Where as only 15% patients were possessing the status of *Agni* as *vishama* 65% of the patients were of *Madhyamvaya*

Sroto Dushti: 100% of volunteers were having *Medovaha Sroto Dusti* while 88.89% volunteers having of *Rasavaha Sroto Dusti*. *Purishavaha Sroto Dusti* was observed in 86.67% patients.

Cardinal Symptoms: In the present study, Tiredness & weakness were presented in 87.5 % patients followed by Sallow complexion and dry skin & Mild proximal weakness in 80 % patients. Slow physical and mental activity was found in 75% patients while Cold intolerance & Tingling in toes and fingers was observed in 72.5% patients. Puffy face, hands, and feet (myxedema) were noticed in 70% patients while Weight gain with poor appetite were found in

67.5% patients. Thinning of scalp and lateral eyebrow hair was presented in 60% patients while Deepened, gruff voice & Slow pulse and shortness of breath were found in 57.5% of patients. Constipation was noticed in 52.5% patients while Paresthesia was found in 50% of

patients. Peripheral edema was noticed in 35% patients while Menorrhagia (later oligomenorrhea or amenorrhea) was found in 25% of patients impaired hearing was found in 22.5% of patients.

| Symptom | Gr. | N | Mean | | X | % Relief | SD | SE | P | SIG |
|--|-----|----|------|-----|-----|----------|--------|--------|-------|-----|
| | | | BT | AT | | | | | | |
| Shallow complexion and dry skin | A | 7 | 1.3 | 0.2 | 1.1 | 84.61 | 0.8756 | 0.2769 | <0.05 | S |
| | B | 10 | 2.6 | 0.6 | 2.0 | 76.92 | 0.4714 | 0.1491 | <0.05 | S |
| | C | 8 | 2.0 | 0.3 | 1.7 | 85 | 1.059 | 0.3350 | <0.05 | S |
| | D | 7 | 1.6 | 0.1 | 1.5 | 93.75 | 1.080 | 0.3416 | <0.05 | S |
| Thinning of scalp and lateral eye brow hair | A | 4 | 0.8 | 0.2 | 0.6 | 75 | 0.8433 | 0.2667 | >0.05 | NS |
| | B | 8 | 1.8 | 0.3 | 1.5 | 83.33 | 0.9718 | 0.3073 | <0.05 | S |
| | C | 7 | 1.3 | 0.1 | 1.2 | 92.30 | 0.9189 | 0.2906 | <0.05 | S |
| | D | 5 | 0.8 | 0.1 | 0.7 | 87.5 | 0.8233 | 0.2603 | >0.05 | NS |
| Cold intolerance | A | 7 | 1.0 | 0.2 | 0.8 | 80 | 0.6325 | 0.2000 | <0.05 | S |
| | B | 9 | 1.8 | 0.5 | 1.3 | 72.22 | 0.6749 | 0.2134 | <0.05 | S |
| | C | 5 | 0.9 | 0.1 | 0.8 | 88.88 | 0.9189 | 0.2906 | >0.05 | NS |
| | D | 8 | 1.4 | 0.1 | 1.3 | 92.85 | 0.8233 | 0.2603 | <0.05 | S |
| Deepened gruff voice | A | 7 | 1.5 | 0.2 | 1.3 | 86.66 | 1.059 | 0.3350 | <0.05 | S |
| | B | 4 | 0.7 | 0.1 | 0.6 | 85.71 | 0.8433 | 0.2667 | >0.05 | NS |
| | C | 5 | 1.1 | 0.3 | 0.8 | 72.72 | 0.9189 | 0.2906 | >0.05 | NS |
| | D | 7 | 1.7 | 0.3 | 1.4 | 82.35 | 0.9661 | 0.3055 | <0.05 | S |
| Slow physical and mental activity | A | 6 | 1.1 | 0.2 | 0.9 | 81.81 | 0.8756 | 0.2769 | <0.05 | S |
| | B | 8 | 1.3 | 0.3 | 1.0 | 76.92 | 0.6667 | 0.2108 | <0.05 | S |
| | C | 8 | 1.3 | 0.1 | 1.2 | 92.30 | 0.7888 | 0.2494 | <0.05 | S |
| | D | 8 | 1.6 | 0.2 | 1.4 | 87.5 | 0.8433 | 0.2667 | <0.05 | S |
| Tingling in toes and fingers | A | 8 | 1.6 | 0.2 | 1.4 | 87.5 | 0.8433 | 0.2667 | <0.05 | S |
| | B | 6 | 1.3 | 0.2 | 1.1 | 84.61 | 0.9944 | 0.3145 | <0.05 | S |
| | C | 6 | 1.1 | 0.1 | 1.0 | 90.90 | 0.9428 | 0.2981 | <0.05 | S |
| | D | 7 | 1.2 | 0.2 | 1.0 | 83.33 | 0.8165 | 0.2582 | <0.05 | S |
| Mild proximal weakness | A | 8 | 1.4 | 0.4 | 1.0 | 71.42 | 0.6667 | 0.2108 | <0.05 | S |
| | B | 8 | 1.1 | 0.1 | 1.0 | 90.90 | 0.6667 | 0.2108 | <0.05 | S |
| | C | 9 | 1.5 | 0.2 | 1.3 | 86.66 | 0.6749 | 0.2134 | <0.05 | S |
| | D | 7 | 1.2 | 0.1 | 1.1 | 91.66 | 0.8756 | 0.2769 | <0.05 | S |
| Slow pulse and shortness of breath | A | 5 | 0.7 | 0.1 | 0.6 | 85.71 | 0.6992 | 0.2211 | >0.05 | NS |
| | B | 5 | 0.8 | 0.1 | 0.7 | 87.5 | 0.8233 | 0.2603 | >0.05 | NS |
| | C | 8 | 1.5 | 0.2 | 1.3 | 86.66 | 0.8233 | 0.2603 | <0.05 | S |
| | D | 5 | 0.7 | 0.1 | 0.6 | 85.71 | 0.6992 | 0.2211 | >0.05 | NS |
| Tiredness, weakness | A | 10 | 2.0 | 0.4 | 1.6 | 80 | 0.5164 | 0.1633 | <0.05 | S |
| | B | 7 | 1.1 | 0.2 | 0.9 | 81.81 | 0.7379 | 0.2333 | <0.05 | S |
| | C | 9 | 1.7 | 0.4 | 1.3 | 76.47 | 0.6749 | 0.2134 | <0.05 | S |
| | D | 9 | 1.4 | 0.2 | 1.2 | 85.71 | 0.6325 | 0.2000 | <0.05 | S |
| Constipation | A | 5 | 0.7 | 0.1 | 0.6 | 85.71 | 0.6992 | 0.2211 | >0.05 | NS |
| | B | 6 | 1.1 | 0.2 | 0.9 | 81.81 | 0.8756 | 0.2769 | <0.05 | S |
| | C | 5 | 1.0 | 0.1 | 0.9 | 90 | 1.101 | 0.3480 | >0.05 | NS |
| | D | 5 | 0.7 | 0.1 | 0.6 | 85.71 | 0.6992 | 0.2211 | >0.05 | NS |
| Weight gain with poor appetite | A | 4 | 0.9 | 0.3 | 0.6 | 66.66 | 0.9661 | 0.3055 | >0.05 | NS |
| | B | 7 | 1.0 | 0.1 | 0.9 | 90 | 0.7379 | 0.2333 | <0.05 | S |
| | C | 6 | 1.1 | 0.3 | 0.8 | 72.72 | 0.7888 | 0.2494 | <0.05 | S |
| | D | 8 | 0.8 | 0.3 | 0.5 | 62.5 | 0.9718 | 0.3073 | >0.05 | NS |
| Menorrhagia (later oligomenorrhea or amenorrh) | A | 3 | 0.4 | 0.1 | 0.3 | 75 | 0.4830 | 0.1528 | >0.05 | NS |
| | B | 1 | 0.2 | 0.1 | 0.1 | 50 | 0.3162 | 0.1000 | >0.05 | NS |
| | C | 1 | 0.2 | 0.1 | 0.1 | 50 | 0.3162 | 0.1000 | >0.05 | NS |
| | D | 4 | 0.8 | 0.2 | 0.6 | 75 | 0.8433 | 0.2667 | >0.05 | NS |
| Paresthesia | A | 5 | 1.0 | 0.3 | 0.7 | 70 | 0.8233 | 0.2603 | >0.05 | NS |
| | B | 5 | 0.6 | 0.1 | 0.5 | 83.33 | 0.5270 | 0.1667 | >0.05 | NS |
| | C | 5 | 0.8 | 0.2 | 0.6 | 75 | 0.6992 | 0.2211 | >0.05 | NS |
| | D | 6 | 0.8 | 0.1 | 0.7 | 87.5 | 0.6749 | 0.2134 | <0.05 | S |
| Impaired hearing | A | 4 | 0.8 | 0.2 | 0.6 | 75 | 0.8433 | 0.2667 | >0.05 | NS |
| | B | 1 | 0.1 | 0.2 | 0.1 | 100 | 0.3162 | 0.1000 | >0.05 | NS |
| | C | 2 | 0.3 | 0.1 | 0.2 | 66.66 | 0.4216 | 0.1333 | >0.05 | NS |

| | | | | | | | | | | |
|--|---|---|-----|-----|-----|-------|--------|--------|-------|----|
| Puffy face, hands, and feet (myxedem) | D | 2 | 0.3 | 0.1 | 0.2 | 66.66 | 0.4216 | 0.1333 | >0.05 | NS |
| | A | 8 | 1.0 | 0.1 | 0.9 | 90 | 0.5676 | 0.1795 | <0.05 | S |
| | B | 8 | 0.9 | 0.1 | 0.8 | 88.88 | 0.4216 | 0.1333 | <0.05 | S |
| | C | 5 | 0.6 | 0.1 | 0.5 | 83.33 | 0.5270 | 0.1667 | >0.05 | NS |
| Peripheral edema | D | 7 | 0.9 | 0.1 | 0.8 | 88.88 | 0.6325 | 0.2000 | <0.05 | S |
| | A | 3 | 0.4 | 0.1 | 0.3 | 75 | 0.4830 | 0.1528 | >0.05 | NS |
| | B | 5 | 0.6 | 0.1 | 0.5 | 83.33 | 0.5270 | 0.1667 | >0.05 | NS |
| | C | 5 | 0.7 | 0.2 | 0.5 | 71.42 | 0.5270 | 0.1667 | >0.05 | NS |
| | D | 1 | 0.2 | 0.1 | 0.1 | 50 | 0.3162 | 0.1000 | >0.05 | NS |

Inter Group Comparison of all Group for Subjective Parameters: (Anova test) Comparative Effect of Drugs on Symptoms of Patients of Hypothyroidism

| Symptoms | ANOVA (Kruskal-wallis statistic) KW | P | Comparison between groups (DUNN'S TEST) | Mean Diff. of ranks | P | S |
|--|-------------------------------------|--------|---|---------------------|--------|----|
| 1. Shallow complexion and dry skin | 5.218 | P>0.05 | A-B | 10.300 | P>0.05 | NS |
| | | | A-C | 7.550 | P>0.05 | NS |
| | | | A-D | 5.550 | P>0.05 | NS |
| | | | B-C | 2.750 | P>0.05 | NS |
| | | | B-D | 4.750 | P>0.05 | NS |
| | | | C-D | 2.000 | P>0.05 | NS |
| 2. Thinning of scalp and lateral eye brow hair | 6.985 | P>0.05 | A-B | 10.350 | P>0.05 | NS |
| | | | A-C | 7.200 | P>0.05 | NS |
| | | | A-D | 1.250 | P>0.05 | NS |
| | | | B-C | 3.150 | P>0.05 | NS |
| | | | B-D | 9.100 | P>0.05 | NS |
| | | | C-D | 5.950 | P>0.05 | NS |
| 3. Cold intolerance | 3.186 | P>0.05 | A-B | 5.50 | P>0.05 | NS |
| | | | A-C | 1.15 | P>0.05 | NS |
| | | | A-D | 5.65 | P>0.05 | NS |
| | | | B-C | 6.65 | P>0.05 | NS |
| | | | B-D | 0.15 | P>0.05 | NS |
| | | | C-D | 6.80 | P>0.05 | NS |
| 4. Deepened gruff voice | 4.662 | P>0.05 | A-B | 7.60 | P>0.05 | NS |
| | | | A-C | 5.35 | P>0.05 | NS |
| | | | A-D | 1.35 | P>0.05 | NS |
| | | | B-C | 2.25 | P>0.05 | NS |
| | | | B-D | 8.95 | P>0.05 | NS |
| | | | C-D | 6.70 | P>0.05 | NS |
| 5. Slow physical and mental activity | 2.496 | P>0.05 | A-B | 1.00 | P>0.05 | NS |
| | | | A-C | 4.00 | P>0.05 | NS |
| | | | A-D | 7.00 | P>0.05 | NS |
| | | | B-C | 3.00 | P>0.05 | NS |
| | | | B-D | 6.00 | P>0.05 | NS |
| | | | C-D | 3.00 | P>0.05 | NS |
| 6. Tingling in toes and fingers | 1.431 | P>0.05 | A-B | 3.55 | P>0.05 | NS |
| | | | A-C | 4.90 | P>0.05 | NS |
| | | | A-D | 5.15 | P>0.05 | NS |
| | | | B-C | 1.35 | P>0.05 | NS |
| | | | B-D | 1.60 | P>0.05 | NS |
| | | | C-D | 0.25 | P>0.05 | NS |
| 7. Mild proximal weakness | 1.233 | P>0.05 | A-B | 0.00 | P>0.05 | NS |
| | | | A-C | 4.60 | P>0.05 | NS |
| | | | A-D | 1.80 | P>0.05 | NS |
| | | | B-C | 4.60 | P>0.05 | NS |
| | | | B-D | 1.80 | P>0.05 | NS |
| | | | C-D | 2.80 | P>0.05 | NS |
| 8. Slow pulse and shortness of breath | 4.905 | P>0.05 | A-B | 4.50 | P>0.05 | NS |
| | | | A-C | 3.90 | P>0.05 | NS |
| | | | A-D | 5.80 | P>0.05 | NS |
| | | | B-C | 8.40 | P>0.05 | NS |
| | | | B-D | 1.30 | P>0.05 | NS |
| | | | C-D | 9.70 | P>0.05 | NS |
| 9. Tiredness, weakness | 5.239 | P>0.05 | A-B | 10.75 | P>0.05 | NS |
| | | | A-C | 4.75 | P>0.05 | NS |

| | | | | | | |
|--|--------|--------|-----|-------|--------|----|
| | | | A-D | 6.50 | P>0.05 | NS |
| | | | B-C | 6.00 | P>0.05 | NS |
| | | | B-D | 4.25 | P>0.05 | NS |
| | | | C-D | 1.75 | P>0.05 | NS |
| 10. Constipation | 0.8331 | P>0.05 | A-B | 3.60 | P>0.05 | NS |
| | | | A-C | 2.40 | P>0.05 | NS |
| | | | A-D | 0.00 | P>0.05 | NS |
| | | | B-C | 1.20 | P>0.05 | NS |
| | | | B-D | 3.60 | P>0.05 | NS |
| | | | C-D | 2.40 | P>0.05 | NS |
| | | | | | | |
| 11. Weight gain with poor appetite | 2.284 | P>0.05 | A-B | 6.0 | P>0.05 | NS |
| | | | A-C | 4.30 | P>0.05 | NS |
| | | | A-D | 6.50 | P>0.05 | NS |
| | | | B-C | 1.70 | P>0.05 | NS |
| | | | B-D | 0.50 | P>0.05 | NS |
| | | | C-D | 2.20 | P>0.05 | NS |
| | | | | | | |
| 12. Menorrhagia (later oligomenorrhea or amenorrhia) | 4.279 | P>0.05 | A-B | 3.80 | P>0.05 | NS |
| | | | A-C | 3.80 | P>0.05 | NS |
| | | | A-D | 2.80 | P>0.05 | NS |
| | | | B-C | 0.00 | P>0.05 | NS |
| | | | B-D | 6.60 | P>0.05 | NS |
| | | | C-D | 6.60 | P>0.05 | NS |
| | | | | | | |
| 13. Paresthesia | 0.4158 | P>0.05 | A-B | 2.10 | P>0.05 | NS |
| | | | A-C | 1.05 | P>0.05 | NS |
| | | | A-D | 0.75 | P>0.05 | NS |
| | | | B-C | 1.050 | P>0.05 | NS |
| | | | B-D | 2.85 | P>0.05 | NS |
| | | | C-D | 1.80 | P>0.05 | NS |
| | | | | | | |
| 14. Impaired hearing | 3.281 | P>0.05 | A-B | 6.60 | P>0.05 | NS |
| | | | A-C | 4.70 | P>0.05 | NS |
| | | | A-D | 4.70 | P>0.05 | NS |
| | | | B-C | 1.90 | P>0.05 | NS |
| | | | B-D | 1.90 | P>0.05 | NS |
| | | | C-D | 0.00 | P>0.05 | NS |
| | | | | | | |
| 15. Puffy face, hands, and feet (myxedem) | 3.031 | P>0.05 | A-B | 1.40 | P>0.05 | NS |
| | | | A-C | 7.10 | P>0.05 | NS |
| | | | A-D | 1.90 | P>0.05 | NS |
| | | | B-C | 5.70 | P>0.05 | NS |
| | | | B-D | 0.50 | P>0.05 | NS |
| | | | C-D | 5.20 | P>0.05 | NS |
| | | | | | | |
| 16. Peripheral edema | 4.898 | P>0.05 | A-B | 3.90 | P>0.05 | NS |
| | | | A-C | 4.60 | P>0.05 | NS |
| | | | A-D | 3.90 | P>0.05 | NS |
| | | | B-C | 0.70 | P>0.05 | NS |
| | | | B-D | 7.80 | P>0.05 | NS |
| | | | C-D | 8.50 | P>0.05 | NS |
| | | | | | | |

Showing effect of drugs on lab investigations (objectives parameters): Paired 't' test

| Investigati on | Gr. | Mean values | | Mean | % | S.D. | S.E. | 't' | P | S |
|-------------------|-----|-------------|------|-------|--------|--------|--------|-------|--------|----|
| | | BT | AT | D.F. | Change | | | | | |
| T3 | A | 1.43 | 1.25 | 0.17 | 11.88 | 0.3869 | 0.1223 | 1.406 | P>0.05 | NS |
| | B | 1.40 | 1.48 | 0.08 | 5.71 | 0.4976 | 0.1574 | 0.508 | P>0.05 | NS |
| | C | 1.42 | 1.37 | 0.05 | 3.52 | 0.2198 | 0.0695 | 0.719 | P>0.05 | NS |
| | D | 1.23 | 1.25 | 0.02 | 1.62 | 0.1964 | 0.062 | 0.322 | P>0.05 | NS |
| T4 | A | 9.42 | 9.35 | 0.065 | 0.69 | 1.282 | 0.4055 | 0.160 | P>0.05 | NS |
| | B | 8.21 | 7.51 | 0.708 | 8.52 | 1.333 | 0.4216 | 0.127 | P>0.05 | NS |
| | C | 7.95 | 8.87 | 0.923 | 11.57 | 1.925 | 0.6087 | 1.516 | P>0.05 | NS |
| | D | 7.53 | 7.55 | 0.026 | 0.34 | 1.740 | 0.5502 | 0.047 | P>0.05 | NS |
| TSH | A | 3.51 | 4.69 | 1.17 | 33.33 | 2.794 | 0.883 | 1.334 | P>0.05 | NS |
| | B | 11.97 | 6.59 | 5.38 | 44.94 | 9.605 | 3.037 | 1.773 | P>0.05 | NS |
| | C | 5.071 | 3.16 | 1.905 | 33.27 | 5.122 | 1.620 | 1.176 | P>0.05 | NS |
| | D | 4.35 | 6.67 | 2.31 | 53.10 | 6.744 | 2.133 | 1.084 | P>0.05 | NS |

Inter group comparison of all group for laboratoty parameters: (Anova test-tukey-kramer multiple comparisons test)




| Investigation | F statistics (Anova) | Tukey-Kramer Multiple Comparisons Test | Mean Diff. | P | S |
|---------------|----------------------|--|------------|--------|----|
| T3 | 0.9682 | A v/s B | 0.2520 | P>0.05 | NS |
| | | A v/s C | 0.1220 | P>0.05 | NS |
| | | A v/s D | 0.1920 | P>0.05 | NS |
| | | B v/s C | 0.1300 | P>0.05 | NS |
| | | B v/s D | 0.0600 | P>0.05 | NS |
| T4 | 1.773 | C v/s D | 0.0700 | P>0.05 | NS |
| | | A v/s B | 0.6430 | P>0.05 | NS |
| | | A v/s C | 0.9880 | P>0.05 | NS |
| | | A v/s D | 0.0910 | P>0.05 | NS |
| | | B v/s C | 1.631 | P>0.05 | NS |
| T4 | 1.773 | B v/s D | 0.7340 | P>0.05 | NS |
| | | C v/s D | 0.8970 | P>0.05 | NS |
| | | A v/s B | 0.6430 | P>0.05 | NS |
| | | A v/s C | 0.9880 | P>0.05 | NS |
| | | A v/s D | 0.0910 | P>0.05 | NS |
| T4 | 1.773 | B v/s C | 1.631 | P>0.05 | NS |
| | | B v/s D | 0.7340 | P>0.05 | NS |
| | | C v/s D | 0.8970 | P>0.05 | NS |
| | | A v/s B | 0.6430 | P>0.05 | NS |
| | | A v/s C | 0.9880 | P>0.05 | NS |

Discussion**Discussion of Pharmacognostical Study:**


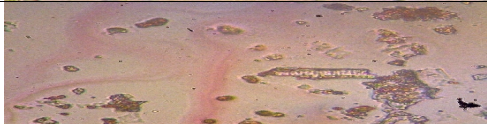
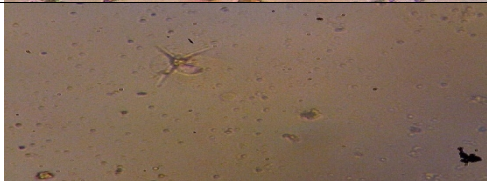
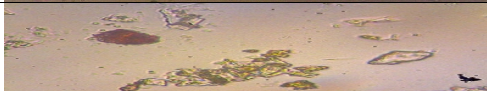
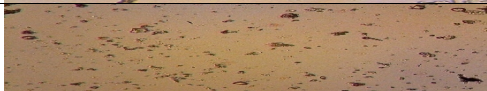

Therefore, the evaluation of medicinal plants scientifically consists proper identification and certain correlation of them with *Ayurvedic* description. A gross study of the plants with it is microscopically, external and internal morphological is merely possible by the study of pharmacognosy. Modern botanists concluded

Brahmi as *Bacopamonnieri* in *Scrophulariaceae* family, *Gandira* as *Coleus forskohlii* in *Lamiaceae* family and *Pippali* as *Piperlongum*. Description of these plant is given in drug review. Discussion of distribution, external and internal morphology, microscopic study, chemical composition of three plants were done in the concerned chapter.

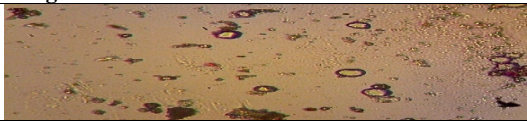
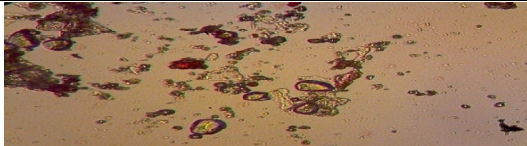
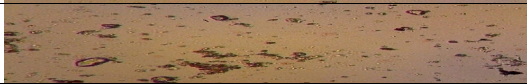



Powder Microscopy of Brahmi powder

| Image | Components (Cell Inclusions) | Staining Reagents |
|---|---|-------------------|
|  | Parenchymatous Cells attached with fibre | Eosin |
|  | Trichome & Xylem Tracheids (Pitted) | Iodine |
|  | Lignified Cell & Stone cells | Safranine |
|  | Xylem Vessels (Unlignified) | Safranine |
|  | Parenchymatous Cells, Fibre, Starch Grains & Scleroid Cells | Iodine solution |
|  | Aseptate fibers | Safranine |

Powder Microscopy of *Grandir* Powder

| Image | Components (Cell Inclusions) | Staining Reagents |
|---|--|-------------------|
|  | Oil Cells | Eosin |
|  | Tracheids of Parenchyma | Safranine |
|  | Rosette Shape calcium oxalate crystals, Starch grains & Proteins | Eosin |
|  | Lignin containing cell | Safranine |
|  | Starch Grains | Iodine solution |
|  | Mucilaginous cells | Methylene Blue |

Powder Microscopy of *Pippalichurna*

| Image | Components (Cell Inclusions) | Staining Reagents |
|---|--|-------------------|
|  | Oil Globules | Eosin |
|  | Starch grains with fragments of Parenchyma | Methylene blue |
|  | Stone cells | Ferric Chloride |
|  | Lignin containing cell | Safranine |
|  | Starch Grains | Iodine solution |
|  | Parenchymal Fragments | Safranine |

Discussion of Analytical Study: Different investigations on various extracts of *Brahmi* reveals the finding. e.g. Carbohydrate, Glycoside, Protein, Phenolic Compound, Alkaloids, Starch, Steroid, Terpenoids, Saponins which proves it is *Bacopamonnieri*. In Analytical Study of *Gandira*, presence of Carbohydrate, Glycoside, Protein, Phenolic Compound, Alkaloids, Starch, Steroid, Terpenoids, Saponins proves it is *Coleusforshkohlii*. In *Pippali* presence of Carbohydrate, Glycoside, Protein, Tannin, Phenolic Compound, Alkaloids,

Starch, Steroid, Terpenoids, Saponins proves it is *Piper longum*. Further HPTLC of these plants was conducted in *Ayushraj Enterprises Pvt. Ltd.* to prove their identity. Descriptions of these plants were done in the concerned chapter.

Discussion on Probable Mode of Action: The fundamentals of *Ayurvedic* pharmacology are capable to give a better scientific lead in mode of the drug action. Pharmacology of *Ayurveda* is based on the theory of *Rasa, Guna, Virya, Vipaka* and *Prabhava* which were the simplest parameters in those days to ascertain the action

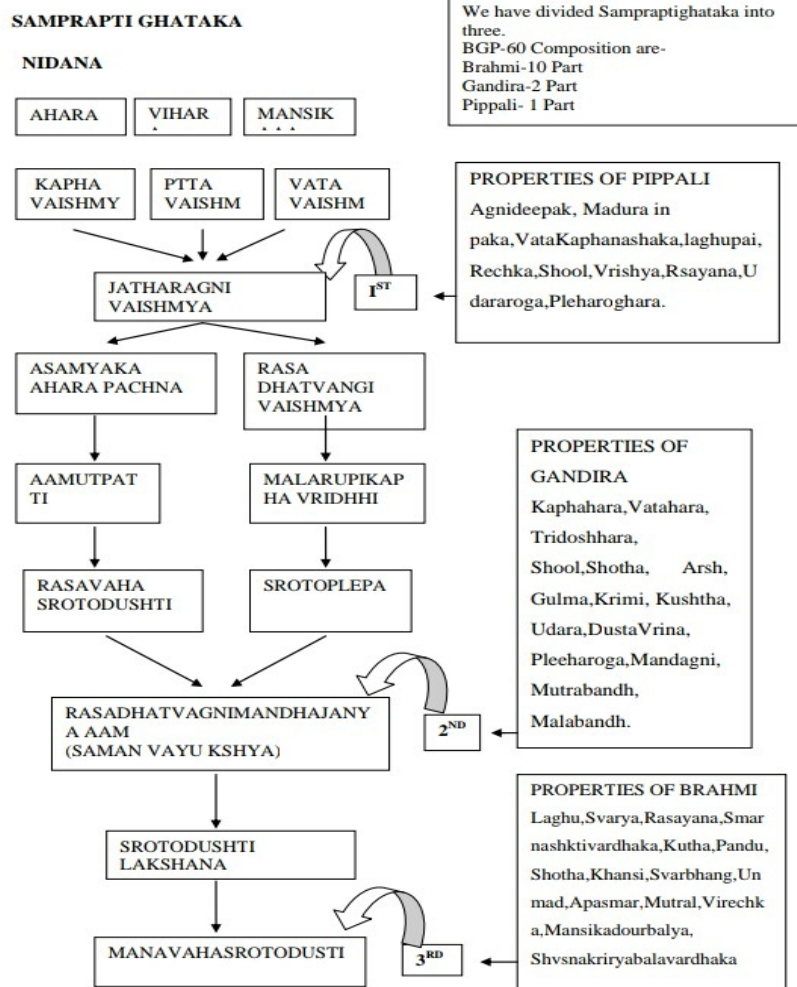
of the drug. According to *Ayurveda*, three rasa are possess in *Brahmi* plant which is *Tikta*, *kshaya* & *Madhura*. Two *rasa* are possessed in

Gandira root which is *Katu* & *Tikta*. *Pippali* fruit has two *rasa*, *Katu* & *Madhura*.

Showing the Probable Action of Rasakarma on Symptoms of Hypothyroidism

| Symptoms of Hypothyroidism | karma of rasa |
|--|---|
| Sallow complexion and dry skin | <i>Tvchya</i> , <i>kusthanashna</i> (<i>Tikta rasa</i>), <i>Tvchaprasadhna</i> (<i>Kshaya</i>) <i>Tvchya</i> , <i>Varnya</i> (<i>madhura</i>) |
| Thinning of scalp and lateral eyebrow hair | <i>Keshya</i> , (<i>madhura</i>) <i>Varnashodhna</i> (<i>Kshaya</i>) |
| Cold intolerance | <i>Kaphanashna</i> (<i>Tikta rasa</i>) <i>Kaphaghna</i> , (<i>Kshaya</i>) <i>Kaphanashana</i> |
| Deepened, gruff voice | <i>Kanthashodhan</i> , (<i>Tikta rasa</i>) <i>Kanthaya</i> , (<i>madhura</i>) <i>Galamyanaashna</i> , <i>Mukhroghara</i> |
| Slow physical and mental activity | <i>Shadindridyaprasadana</i> (<i>madhura</i>) <i>Aalsyanashna</i> |
| Tingling in toes and finger | <i>Dahaprashmana</i> (<i>Tikta rasa</i>) <i>Dahaprashmana</i> (<i>madhura</i>) |
| Mild proximal weakness | <i>Shadindridyaprasadana</i> (<i>madhura</i>) |
| Tiredness, weakness | <i>Sarvadhaturvardhana</i> (<i>madhura</i>) |
| Constipation | <i>Anulomana</i> , (<i>madhura</i>) |
| Weight gain | <i>Lekhna</i> , <i>Jaliadhatur-updhatu-mala soshna</i> , (<i>Tikta rasa</i>) <i>Sarvadhaturushoshna</i> , <i>Lekhna</i> (<i>Kshaya</i>) <i>Manslekhana</i> , <i>Sthultanashna</i> , <i>Lekhna</i> |
| poor appetite | <i>Deepana</i> . <i>Pachna</i> (<i>Tikta rasa</i>) <i>Anulomana</i> , (<i>madhura</i>) <i>Deepana</i> , <i>Rochna</i> , <i>Pachna</i> |
| Menorrhagia (later oligomenorrhea or amenorrhea) | <i>Raktaprasadana</i> (<i>Tikta rasa</i>), <i>Rakta pitta prashman</i> (<i>Kshaya</i>) <i>Raktastravkara</i> , <i>Aatravajana</i> |
| Paresthesia | <i>Nadiuttejnanasahka</i> , (<i>Kshaya</i>) <i>Indriyotejana</i> |
| Impaired hearing | |
| Puffy face, hands, and feet (myxedema) | <i>Sothshar</i> (<i>Tikta rasa</i>) <i>Sothnashna</i> (<i>katu</i>) |
| Peripheral edema | <i>Sothshar</i> (<i>Tikta rasa</i>) <i>Sothnashna</i> (<i>katu</i>) |

Discussion on Probable Mode of Action of BGP-60 (*Kalapityog*)



Mode of Action to Modern Aspect

Brahmi: Endocrine effects-BME (200 mg/kg orally) increased the thyroid hormone, T4, by 41% in mice. T3 was not stimulated, suggesting that the extract may directly stimulate synthesis and/or release of T4 at the glandular level while not affecting conversion of T4 to T3.

Gandira: Forskolin is the main active ingredient in *coleus forskohlii*. Forskolin has demonstrated the ability to increase thyroid hormone production and stimulate thyroid hormone release. It also activates production of cyclic AMP. It is also useful as adjuvant with the synthetic drugs to increase production of thyroid gland,

Pippali: *Pippali* kindles *bhutagni* in the liver, Improving liver function, and is a metabolic stimulant, aiding the thermogenic response by increasing the level of thyroid hormone. It increases the absorption of selenium, whose deficiency can impair thyroid function because conversion of T4 into T3 is catalysed by specific seleno proteins

Conclusion: Though any disease condition is not described in *Ayurveda* which is similar to Hypothyroidism, it can be correlated with some conditions like *Kaphaja Grahani* (*Charaka Chikitsa* 15/70), *Kaphaja Pandu* (*Charaka Chikitsa* 16/23-24), *Bahudoshavastha* (*Charaka Sutra* 16/13-16) & *Saman Vayu Kshaya* described in the classics. Pathogenesis of hypothyroidism according to the principles of *Ayurveda* can be interpreted by Dysfunctioning of the *Agni* particularly *Dhatvagni*. Hypothyroidism is a psychosomatic disease & one of the most triggering factors of disease is over-worry (*Atichintana*). There is strong correlation between etiopathogenesis of disease & over-worry. In the present study, *BGP-60* Drugs was found more effective in thyroid function tests. *Agnideepak*, *Madura in paka*, *Vata Kaphanashaka*, *laghupai*, *Rechka*, *Shool*, *Vrishya*, *Rsayana*, *Udararoga*, *Pleharoghara*. *Pippali* Drug was found significant results. *Kaphahara*, *Vatahara*, *Tridoshhara*, *Shool*, *Shotha*, *Arsh*, *Gulma*, *Krimi*, *Kushtha*, *Udara*, *Dusta* *Vrina*, *Pleeharoga*, *Mandagni*,

Mutrabandh, *Malabandh*. *Gandira* Drug Drugs was found significant results. *Laghu*, *Svarya*, *Rasayana*, *Smarnashktivardhaka*, *Kutha*, *Pandu*, *Shotha*, *Khansi*, *Svarbhang*, *Unmad*, *Apasmar*, *Mutral*, *Virechka*, *Mansikadourbalya*, *Shvsnakriryabalavardhaka* *Bramhi* Drug was found significant results.

Though all treatment group provided improvement on Signs & Symptoms of Hypothyroidism which was statistically Looking the chronic nature and gradual onset of the disease, sufficient duration is required to cure *Ama* and *Agni mandya* at *Dhatu* level. Results could have been more effective if study would have been done for longer duration

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