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ORIGINAL ARTICLE **OPEN ACCESS**

The Impact of Ayurvedic Interventions on Primary Hypothyroidism with Obesity: A Focus on critical analysis of *Krimighnadi Kashaya* as a *Shamanaoushadhi* and *Shakotaka Taila* for *Pratimarsha Nasya*

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OPEN ACCESS

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A B S T R A C T

Abstract:

Primary hypothyroidism or underactive hypothyroidism is a condition where the thyroid gland functions affected with elevation in thyroid stimulating hormone (TSH) >10 mU/L with free t4 level below the normal range exhibiting features like weight gain, dry skin, cold intolerance, depression etc. The prognosis of the disease has a wider impact on other system like respiratory, cardiac, gastrointestinal, metabolic, skin, renal and musculoskeletal systems exhibiting various clinical features.

In Primary hypothyroidism with Obesity as per *Ayurveda Samprapti*, *Aharaja*, *Viharaja*, *Manasika* and *Jatajanya nidana's* acts as a *Moola karana* in *Vyadhi utpatti*, causing *Vruddi* of *Kapha, Vata Dosha's* and *Kshaya* of *Pitta,* leading to *Agni vaishamyata* (*Jatharagni)* further causing *Rasa* and *Medho dhatvagni vyatyasa.* In Modern science the clinical pathology is correlated to Gut brain thyroid axis disturbances linking to the disease manifestation.

In present clinical study, the Chikitsa principle is *Nidana parivarjana, Shamana* by *Krimighnadi Kashaya* along with *Shakotaka Taila* for *Pratimarsha Nasya*, fuurther implementation of proper *Dinacharya* and *Pathya Apathya* which help in managing the *Vyadhi* by increasing *Agni bala*, balancing the *tridosha*, *Rasa* and *Medo dhatu* functions.

Key words: Primary Hypothyroidism with Obesity, *Agnivikara*, *Tridosha*, Gut Brain Thyroid Axis *Samprapti, Shamana, Pratimarsha Nasya*

INTRODUCTION

Thyroid disease circumscribes various conditions like hypothyroidism, hyperthyroidism, auto immune thyroid disease, thyroid nodules and thyroid cancer where in the function, size or structure of the thyroid gland will be affected. In women, the prevalence of primary hypothyroidism was higher, at 11.4%, when compared with men, in whom the prevalence was 6.2%[1]. An Indian study 625 consecutive primary hypothyroidism patients grouped in that Obesity patients were noted more, among them overt hypothyroidism was present in 33% and subclinical hypothyroidism in 11% subjects[2].

Hypothyroidism is defined as a deficiency of Thyroid hormones or a disruption of the hypothalamus-pituitary-thyroid axis[3].Hypothyroidism can be primary when there is thyroid gland disease or secondary to hypothalamic or pituitary dysfunction[3]. In modern science hypothyroidism has a link in obesity pathology[5] even in Ayurveda Primary hypothyroidism with Obesity can be correlated to the *RasapradoshajaVikara*.

To heal this condition, *Krimighnadi Kashaya*[6] internally along with *Shakotaka Taila*[7]as a *Pratimarsha Nasya* may be helpful. Hence, this critical analysis of the drug is carried out with an aim to understand the management of Primary Hypothyroidism with Obesity as per Ayurvedic principles.

OBJECTIVES:

1) To understand the possible actions of *Krimighnadi Kashaya* as a *Shamanoushadi* and *Shakotaka Taila* for *Pratimarsha Nasya* in the management of Primary Hypothyroidism with Obesity.
2) To Know the Phytochemical analysis of the drugs.

MATERIALS AND METHODS

All the *Ayurvedic* literature, modern literature, contemporary text including the websites, journals and articles both printed, online data collected to analyse and interpret about the disease and treatment further documented for the intended study.

TREATMENT PLAN

GROUPING:

Group A: *Shakotaka Taila* for *Pratimarsha Nasya* 2 *bindu* -2 drops in each nostril with Trial drug- *Krimighnadi Kashaya* 50 ml 2 times before food morning and night.

Group B: *Shakotaka Taila* for *Pratimarsha Nasya* 2 *bindu*- 2 drops in each nostril with Control drug- *Phalatrikadi Kashaya* 50 ml 2 times before food morning and night.

Table No 1: Plan of Intervention

Method		**Intervention**	**Dose**	**Treatment Days**	**Follow Up day**	**Final Assessment**
Nasya-Pratimasha	GROUP A GROUP B	***Shokotha Taila***	2 *Bindu*-2 drops each nostril Before food	60	30th day in between	61st day
Shamana	GROUP A	***Krimighnadi Kashaya***	50ml-0-50ml Before food	60	30th day in between	61st day
	GROUP B	*Phalatrikadi Kashaya*				

STUDY DESIGN

A Randomized controlled study; Parallel Study; With a Single blinding

SAMPLING TECHNIQUE

- The subjects who fulfill the inclusion criteria and complying with the Informed Consent will be selected using random sampling technique.
- The randomization scheme will be generated by using the website randomization.com

SAMPLE SIZE

Since there are no such studies based on this combination of drugs, assuming the effect size is 50% effective. At 95% confidence level, 80% power with an allocation ratio of 1:1. The sample size per group is 64. Considering the 7% drop-out rate the sample size per group is 70. Therefore 140 patients will be recruited and randomized into two groups. The sample size is estimated using G*Power 3.1.9.7 software. Note: (Hence formula of sample size is not required to put here)

CRITERIA OF THE STUDY:

A. SCREENING:

A screening form will be prepared with all aspects of history, signs and symptoms of Primary Hypothyroidism with Obesity and laboratory investigation will be conducted to arrive at proper diagnosis and to rule out major illness.

B. DIAGNOSTIC CRITERIA

a. **Objective criteria**

Lab investigation: Pre-tests- FBS, PPBS, LFT, USG abdomen
Specific study tests-Lipid Profile, Thyroid profile (Serum) TSH, fT3, fT4, BMI

a. **Subjective criteria- will be assessed as per following scales:**

Symptoms	**Signs**
• Tiredness/ Weakness • Dry skin • Feeling cold • Hair loss • Difficulty in concentrating and poor memory • Constipation- CTCAE -Common Terminology Criteria for Adverse Events grading of constipation • Weight gain with poor appetite • Hoarse voice- GRBAS scale • Menorrhagia – Menstrual assessment Chart • Paraesthesia- • Dyspnea- Modified Medical Research Council (mMRC) dyspnea scale • Impaired hearing- WHO's Grades of hearing impairment	• Dry coarse skin • Cool peripheral extremities • Puffy face • Diffused alopecia • Bradycardia • Peripheral edema • Delayed tendon reflex • Carpel tunnel syndrome (CTS grading scale)

- Physical factor assessment of Blood pressure.
- Zulewski's Clinical Score for Hypothyroidism[8].
- Obesity Assessment Score[9]- as per BMI scale.
- Waist Circumference[10] for obese >94cm in male and waist circumference > 80 cm in women - pre and post treatment.
- Waist Hip Ratio[10] for obese >0.89 for men and >0.81 for women - pre and post treatment.

C. <u>INCLUSIONCRITERIA:</u>

a. Subjects fulfilling the diagnostic criteria.
b. Subjects belonging to age group of 18 to 60 years of all gender will be included.
c. Both fresh and treated cases of hypothyroidism will be included.
   A - Freshly detected and untreated cases of hypothyroidism.
   B - Established and treated cases of hypothyroidism also who are ready to discontinue the earlier medication with Flush out period of 15 days.
d. Patients with hypothyroidism BMI > 25.
e. Subjects with serum TSH > 5 to < 10 ml IU/L and >10ml-(Primary Hypothyroidism) with decrease fT4 and fT3.
f. Who signed the informed consent.

D. <u>EXCLUSIONCRITERIA</u>

a. Subjects with congenital hypothyroidism, chronic history of hypothyroidism (>5 yrs.) and secondary hypothyroidism/ tertiary hypothyroidism.
b. Subjects with any chronic systemic disorders like cerebrovascular accidents, ischemic heart diseases, uncontrolled diabetes mellitus, uncontrolled hypertension, any active malignancies, chronic renal failure, radiation therapy etc., which interrupt the present intervention.
c. Subjects who have undergone thyroid surgery.
d. Pregnant and lactating women.
e. Diagnosed cases of neoplastic conditions, toxic goiter, drug induced hypothyroidism will also be excluded.
f. Who doesn't sign the informed consent.

DISCUSSION

- **Highlights on Thyroid gland – Anatomy and Physiology:**

The Gland is having butterfly shape, and is located inferior to the larynx, anterior to the trachea and two lobes are connected by the isthmus. Pyramidal lobe is the third lobe variations found in 50% cases. Normal mass is 15 to 20 grams

and microscopic structure shows spherical masses called follicles. A secretary substance is present in follicle called colloid and made ofa glycoprotein called thyroglobulin. Thyroglobulin produces thyroid hormones, which are Triiodothyronine (T3), Tetra iodothyronine (T4)and Calcitonin[11].

- **Role of thyroid hormones:**

Basically, governs cellular metabolic activity, blood flow, cardiac output with rate and secretion of digestive juices. Regulates the metabolic actions by stimulating carbohydrate, fat and protein metabolism. Further even regulates development and growth of nervous tissue and bones.

- **Normal plasma levels of thyroid hormones[12]**
  - TSH - 0.5 – 4.7mmu/L (Secreted by anterior pituitary gland and it helps in the secretion of T3 and T4 from thyroid gland).
  - Thyroxine (T4) - 58-140 nmol/L/
  - Tri-iodothyronine (T3) -0.92 – 2.78nmol/L
  - Free T4 (FT4) -10.3 -35pmol/L
  - Free T3 (FT3) -0.22 -6.78nmol/L

In Hypothyroidism the levels are characterized by increase in level of TSH with either reduced T3 and T4 or normal T3 and T4.

- **Gut-Brain-Thyroid Axis Vs HPT Axis in Primary Hypothyroidism with Obesity:**

Gut-Brain-Thyroid Axis in gut there are two hormones Cholecystokinin secreted from endocrine cells of Duodenum and Ghrelin secreted from oxyntic cells of Stomach which control the secretion of thyroid hormones from the thyroid gland. Gut Brain Thyroid Axis is a complex interaction between gut micro biome, the brain and thyroid gland. Gut micro biome potentially influences thyroid function. Here impaired gastrointestinal motility and increased intestinal permeability which creates favourable condition for SIBCO- small intestinal bacterial colonization and overgrowth and promotes bacterial translocation from intestinal epithelial barrier to lymph nodes. Gut micro biome in primary hypothyroidism shows considerable differences of 4 intestinal bacteria in high-rate Villanella, Parapevotella, Nisseria and Reinheimer. Faecal microbiota transplantation shows decrease in thyroxine levels[13].

- **Hypothalamus Pituitary Thyroid axis,** in obesity-

Increased TRH secretion:
In primary hypothyroidism, the hypothalamus releases more Thyrotropin Releasing Hormone (TRH), thyroid hormone levels are low in rate which can indirectly affect the HPO axis by impacting the pulsatile release of Gonadotropin Releasing Hormone (GnRH) and causing pathology.

Elevated prolactin levels:
Elevated TRH can also stimulate prolactin production in the pituitary gland, which can further disrupt the HPO axis by inhibiting GnRH release and causing the pathology.

Leptin resistance:
Visceral fat accumulation an obesity, can lead to leptin resistance, a hormone that normally regulates appetite and energy balance, further impacting the hypothalamic regulation of the HPO axis and lead to the manifestation of the disease pathology.

Insulin resistance:
Insulin resistance is the main hindrance happening in the disease pathology, which can also contribute to hormonal imbalances affecting the HPO axis.

Shamanoushadi *actions here like Deepana*, *Pachana* etc; of individual drugs as explained above, to rectify the *Agnidushti* further leading to *rasapradoshaja vvyadhi. Kapha-Vatahara-pittavardhaka* drugs with *Medohara* and *Srotoshodhaka* actions drugs are utilised to treat the present condition.

Pratimarsha Nasya actions: *Pratimarsha Nasya* is one such preventive technique as well as therapeutic measure which can pacify the aggravated *dosha's* and stabilize. *Pratimarsha nasya* can be used for *rechana*, *tarpana* and *shamana* purposes.

Drug Review

***Shakotaka Taila* and *Krimighnadi Kashaya* is as follows,**

***ShakhotakaTaila*[7]**

- *Tila Taila- 1 part*
- *ShakotakaTwakChoorna -1/4th part to Tila*
- *Jala-* 4 parts

Mixture will be boiled till *Taila siddhi lakshanas- Mrudu Paka* is achieved, later stored in the glass container then later packed to 10ml air tight container.

Table No.2:*Rasapanchaka* of*Shakotaka*[7,14]

Dravya	***Rasa***	***Guna***	***Veerya***	***Vipaka***	***Doshaghnata***	***Karma***
Shakotaka	*Tikta Kashaya*	*Laghu Rooksha*	*Ushna*	*Katu*	*Vatakapha nashaka*	*Medohara Grahi Vatanulomaka Vranashodhana Vishaghna Jwaraghna*

Shakotaka

Part Used-*Moola, Twak* and *Beeja*

***Tila*[15]**

Sesamum indicum- Botanical Name, Family- *Pedaliaceae*

Rasa-Madhura, Kashaya, Tikta

Guna-Guru, Snigdha

Karma-Yogavahi, Dravyantarasanyogatridoshashamaka

Usage- *Ushna- Deepana.*

Part Used-*Beeja*

The above details help us to understand the actions of anti-oxidant[16] and anti-inflammatory actions[16] that helps in healing the present case.

***Krimighnadi Kashaya*[6]**

Table No.3: Details of *Krimighnadi Kashaya*

Sl.No	Name	Botanical Name	Part used	Proportion
1	*Krimighna (Vidanga)*	*Embeliaribes*Burm f.	Berries or roots	1 part
2	*Haritaki*	*Terminalia chebula*Retz.	*Phala*	1 part
3	*Vibhitaki*	*Terminalia bellerica*Roxb.	*Phala*	1 part
4	*Amalaki*	*Embelica officinalis* Gaertn.	*Phala*	1 part
5	*Ajaji (Jeeraka)*	*Cuminum Cymium* L.	*Bheeja*	1 part
6	*Katuki*	*Picrorhizakurrooa*Royle Ex Benth.	Roots, stems Leaves extract	1 part
7	*Vyosha (trikatu)*	*Zingiber officinale* Roscoe. *Piper nigrum* L. *Piper longum* Linn.	Roots and Fruits	1 part each
8	*Amrutha*	*Tinospora cordifolia* Willd. Miers.	Stem	1 part

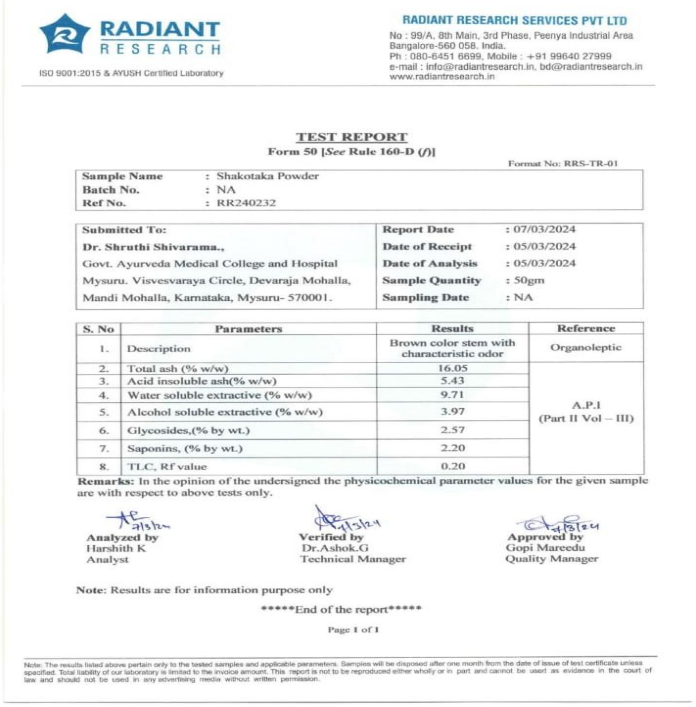
Table No. 4: *Rasapanchaka* of *Krimighnadi Kashaya*[16]

Dravya	***Rasa***	***Guna***	***Veerya***	***Vipaka***	***Doshaghnata***	***Karma***
Krimighna (Vidanga)	*Katu Kashaya*	*Lagu Rooksha Teekshna*	*Ushna*	*Katu*	*Kapha vatashamaka*	*Deepana Pachana Krimighna*
Haritaki	*Lavanavarjitapancharasa*	*Laghu Rooksha*	*Ushna*	*Madhura*	*Kaphavatashamaka*	*Deepana Pachana Yakrututtejaka Mrudurechaka Krimighna*
Vibhitaki	*Kashaya*	*Laghu Rooksha*	*Ushna*	*Madhura*	*Tridoshagna Kaphashamaka*	*Deepana Anulomana Krimighna Rechana Trishnanigraha*
Amalaki	*Lavanavarjitapancharasa Amlapradhana*	*Guru Rooksha Sheeta*	*Sheeta*	*Madhura*	*Tridoshagna pittanashaka*	*Rechana, Deepana Anulomana Sthambana Sramsana*
Ajaji (Jeeraka)	*Katu*	*Laghu Rooksha*	*Ushna*	*Katu*	*Kaphavatashamaka Pittavardhaka*	*Deepana Pachana Vatanulomana Shoola prashamana*
Katuki	*Tikta*	*Rooksha Laghu*	*Sheeta*	*Katu*	*Kaphapittahara*	*Rechana Deepana Pittasaraka Krimighna*
Vyosha - Trikatu	*1)Katu*	*Laghu Snigdha*	*Ushna*	*Madhura*	*Kapha vata shamaka*	*Shothahara Sheetaprashamana Aamapachana*
Shunti	*2) Katu*	*Laghu Snigdha Teekshna*	*Anushnasheeta*	*Madhura*	*Vatashamana*	*Yakrututtejaka*
Pippali						*Agnimandhya ajeerna*
Maricha	*3) Katu*	*Laghu teekshna*	*Ushna*	*Katu*	*Kapha shamana*	*Yakrututtejaka Vatanulomana Deepana Krimighna*
Amrutha	*Tikta Kashaya*	*Guru Snigdha*	*Ushna*	*Madhura*	*Tridoshashamaka*	*Agnimadhya, Trishana, Chardhi, Amlapitta, Grahani hara*

By the detail understanding it helps to substantiate that all the 8 ingredients of the *Shamanoushadhi* which proves Antioxidant, Anti Toxin, Immunomodulatory, Hepatoprotective and Anti-inflammatory actions as per many of the research articles[17-33] may help the clinician to understand its actions and treating present condition.

Hence by the article interpretation, it can be put forth that these *Yoga's* (Formulations) promotes functionality aspects of *Jatharagni*, *Dhatvagni* which may help in curing *Rasapradoshajavikara.*

Phytochemical Analysis Report of *Shakotaka Taila:*



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TEST REPORT

Form 50 [*See* Rule 160-D (*f*)]

Format No: RRS-TR-01

Sample Name	: Shakotaka Powder
Batch No.	: NA
Ref No.	: RR240232

Submitted To:	**Report Date** : 07/03/2024
Dr. Shruthi Shivarama.,	**Date of Receipt** : 05/03/2024
Govt. Ayurveda Medical College and Hospital	**Date of Analysis** : 05/03/2024
Mysuru. Visvesvaraya Circle, Devaraja Mohalla,	**Sample Quantity** : 50gm
Mandi Mohalla, Karnataka, Mysuru- 570001.	**Sampling Date** : NA

S. No	Parameters	Results	Reference
1.	Description	Brown color stem with characteristic odor	Organoleptic
2.	Total ash (% w/w)	16.05	A.P.I (Part II Vol – III)
3.	Acid insoluble ash(% w/w)	5.43	
4.	Water soluble extractive (% w/w)	9.71	
5.	Alcohol soluble extractive (% w/w)	3.97	
6.	Glycosides,(% by wt.)	2.57	
7.	Saponins, (% by wt.)	2.20	
8.	TLC, Rf value	0.20	

Remarks: In the opinion of the undersigned the physicochemical parameter values for the given sample are with respect to above tests only.

Analyzed by
Harshith K
Analyst

Verified by
Dr.Ashok.G
Technical Manager

Approved by
Gopi Mareedu
Quality Manager

Note: Results are for information purpose only

*****End of the report*****

Page 1 of 1

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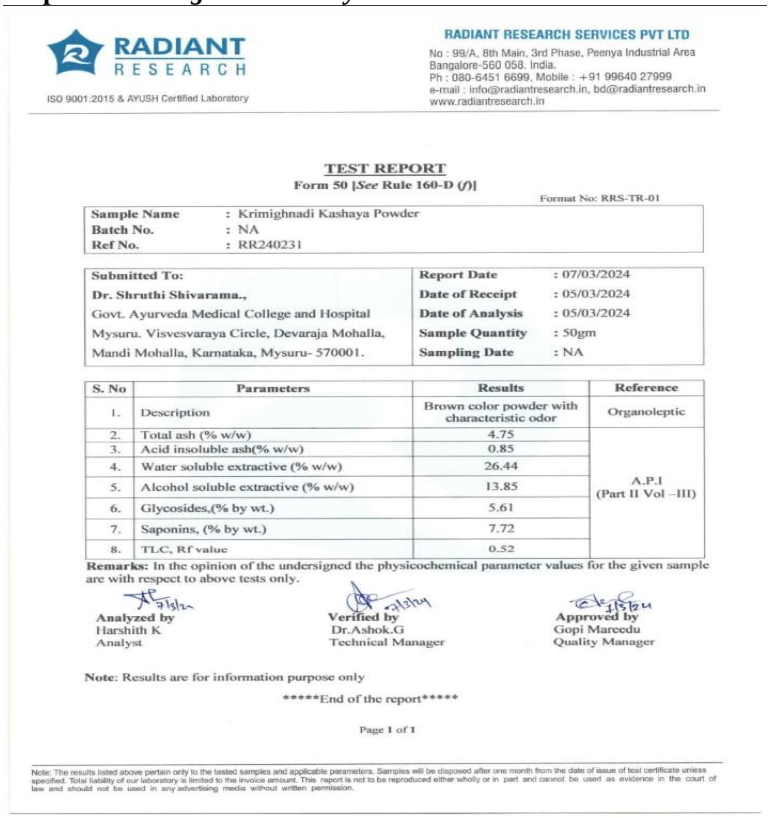
Phytochemical Analysis Report of *Krimighnadi Kashaya:*



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TEST REPORT

Form 50 [*See* Rule 160-D (*f*)]

Format No: RRS-TR-01

Sample Name	: Krimighnadi Kashaya Powder
Batch No.	: NA
Ref No.	: RR240231

Submitted To:	**Report Date** : 07/03/2024
Dr. Shruthi Shivarama.,	**Date of Receipt** : 05/03/2024
Govt. Ayurveda Medical College and Hospital	**Date of Analysis** : 05/03/2024
Mysuru. Visvesvaraya Circle, Devaraja Mohalla,	**Sample Quantity** : 50gm
Mandi Mohalla, Karnataka, Mysuru- 570001.	**Sampling Date** : NA

S. No	Parameters	Results	Reference
1.	Description	Brown color powder with characteristic odor	Organoleptic
2.	Total ash (% w/w)	4.75	A.P.I (Part II Vol –III)
3.	Acid insoluble ash(% w/w)	0.85	
4.	Water soluble extractive (% w/w)	26.44	
5.	Alcohol soluble extractive (% w/w)	13.85	
6.	Glycosides,(% by wt.)	5.61	
7.	Saponins, (% by wt.)	7.72	
8.	TLC, Rf value	0.52	

Remarks: In the opinion of the undersigned the physicochemical parameter values for the given sample are with respect to above tests only.

Analyzed by
Harshith K
Analyst

Verified by
Dr.Ashok.G
Technical Manager

Approved by
Gopi Mareedu
Quality Manager

Note: Results are for information purpose only

*****End of the report*****

Page 1 of 1

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By the detailed analysis report it interprets that the values of both preparations are under significance level with reference to API guidelines. Hence both the drugs are used for trial clinical study to prove its benefits over treating the present case.

CONCLUSION

With understanding the pathology of the disease its interaction over Gut thyroid brain axis and Hypothalamus thyroid pituitary axis along with the critical analysis of Ayurveda medicines ie; *Krimighnadi Kashaya* as *Shamana oushadhi* and *Shakotakataila* for *Pratimarsha Nasya* may prove to be beneficial in the clinical research over the subjects of Primary Hypothyroidism with Obesity.

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