



ORA-Clinical Research

EFFECT OF SHIGRU (*MORINGA OLEIFERA* LINN.) PATRA CHOORNA TABLET IN THE MANAGEMENT OF SUBCLINICAL HYPOTHYROIDISM – A SINGLE ARM OPEN LABELED CLINICAL TRIAL

¹SHUBHAM K, ^{2*}ARUN C

ABSTRACT :

Background: Due to increasing global incidence of Thyroid disorders and their effect on day today life, numerous studies are being conducted to identify potential treatment for *Anukta vyadhis*. So many drugs have been known for Thyroid controlling properties; but researches regarding its clinical efficacy are less. **Objectives:** The purpose of this study was to evaluate the effectiveness of *Shigru (Moringa oleifera Linn.) Patra churna* tablet in the management of Subclinical Hypothyroidism. **Materials & Methods:** In this single arm open labeled clinical trial, all eligible participants were assigned to receive the intervention without randomization. Patients visiting Specialty OPD of KLE Ayurveda Hospital, Belgavi with signs & symptoms of Subclinical hypothyroidism like weight gain, hair-fall, edema, irregular menstrual cycle and 30 patients of 20 to 60 years age group of either sex without any history of Thyroid related disease, Diabetes Mellitus or Hypertension were included; TSH value above normal range but below 10 IU/L. *Shigru patra churna* tablet was given 1 gm twice a day before food for period of 42 days. The assessment of changes observed in Thyroid profile as well as in Anthropometrical changes like waist circumference and weight loss and clinical symptoms like *Keshapatana* (Hairfall), *Medovridhhi*(gradual weight loss), *Shotha* (Facial or generalized edema), *Aniyamita artava* (Menstrual disturbance), *Klama* (Lethargy or easy fatigue) was carried out. **Results:** After 42 days of intervention, Thyroid profile, especially TSH and other parameters were significantly decreased when compared with baseline. No adverse drug reaction was reported during and after the intervention with the use of study drug. **Conclusion:** *Shigru patra churna* was effective in the management of subclinical hypothyroidism and free from any adverse effect on patients.

KEYWORDS: Sub-clinical hypothyroidism, single drug therapy, *shigru*, *moringa*, clinical study.

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Corresponding Author Email:

arunchougale.kaher@kleayurworld.edu.in

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1. INTRODUCTION-

Thyroid diseases are the commonest abnormalities among endocrine dysfunctions in India as well as worldwide. The prevalence of thyroid disorders in women aged 20–45 years is high.[1] Thyroid diseases have substantial influence on community health due to long term morbidities; it may include Thyroiditis, Thyroid Nodules, Goiter & Thyroid Malignancy. It is more common in women, white and Latin Americans. More than 90% of hypothyroidism reflects primary dysfunction of thyroid gland itself,[2] so managing the disease with an effective and efficient plan is essential. A significant percentage of individuals evaluated will exhibit thyroid malfunction, with 10% having subclinical hypothyroidism and 1% having preclinical hyperthyroidism. The prevalence of unrecognized overt thyroid disease is minimal.[3]

Subclinical Hypothyroidism by definition biochemically refers to biochemical evidence of Thyroid hormone deficiency in the patients who have few or no apparent clinical features of hypothyroidism [4] with or without cardinal symptoms of Hypothyroidism. In the general population, the prevalence is 4–10%, and in women over 60, it can reach 20%. Indians have been found to have slightly higher overall prevalence & studies have shown prevalence of 20% in postmenopausal females & 53% in individuals with metabolic syndrome.[5]

Ayurveda is traditional system of medicine in subcontinent of India which holds large number of remedies that can be useful in the treatment of Thyroid related diseases also their related complaints. There is

increased research in alternative science for safe & economical treatment protocol for most of the diseases. Based on its symptomatology Subclinical Hypothyroidism is correlated with *Rasa pradoshaja vikara* (*Rasa dhatu* related diseases) or *Mandagni* (reduced digestive fire). With its wide inventory of remedies, *Ayurveda* may be able to treat thyroid related conditions in a way that is both safe and effective, with few side effects and an overall improvement in quality of life.

Shigru (*Moringa oleifera* Linn.) is widely mentioned in *Nighantu's* (glossary of words) like *Bhavprakash Nighantu*, *Raj Nighantu*, *Dhanvantari nighantu* etc. It is *Katu* (pungent) and *Tikta* (bitter) in *rasa*, *Ushna* in *veerya* (hot potency), with *Katu vipaka* (maturing of food) and *Vata-Kaphahara* action. The drug *Shigru* possess *Teekshna guna* (penetrating action). In *Bhavprakash Nighantu* it is explained as “*medo-apachiganda haret*” (reduces fat-cervical lymphadenitis-diseases related to thyroid) which means it eradicates mentioned diseases.[6] In *Charaka Samhita* is it mentioned under *Krimighna* (anthelmintic), *Swedopaga* (induces perspiration), *Shirovirechanopaga gana* (cleansing head)[7]. Hence *Shigru patra* is selected for this clinical trial to see the efficacy with help of Hematological as well as parameters like weight loss, inch loss and *Ayurvedic* parameters like *Keshapatana* (hairfall), *Medovridhi* (increased fat deposition), *Shotha* (oedema), *Aniyamita-artava* (irregular menstrual cycle) & *Klama* (fatigue) of trial drug through approved clinical research proforma.

In vivo study done in Adult male & Female Rats with extract of *Moringa oleifera* leaves suggest that it helps in regulation of Thyroid hormone status and another interventional study where 5 gm of leaves were given in patients of Hypothyroidism, it showed tremendous changes in thyroid profile.[8] In a recent pilot study, the Ayurvedic formulation containing *Kanchanara Guggulu* and *Varunadi Kashaya* was administered to patients with subclinical hypothyroidism, conceptualized as *Kaphavrita Udanavata*. The treatment showed significant improvements in clinical symptoms and a notable reduction in TSH levels, indicating its potential efficacy in managing early thyroid dysfunction.[9] A double-blind, randomized placebo-controlled trial investigated the efficacy and safety of *Ashwagandha* (*Withania somnifera*) root extract in patients with subclinical hypothyroidism. Over an 8-week period, participants receiving 600 mg daily of the extract exhibited significant improvements in thyroid function, including decreased serum thyroid-stimulating hormone (TSH) and increased levels of triiodothyronine (T3) and thyroxin (T4), suggesting that *Ashwagandha* may help normalize thyroid indices in this population.[10] Based on both Ayurvedic principles and emerging clinical evidence, the use of a single-herb formulation offers a focused therapeutic approach in the management of subclinical hypothyroidism. In particular, herbs with *deepana*, *pachana*, and *medohara* properties have shown potential in correcting the underlying doshic imbalance—primarily *Kaphavrita Udanavata*, a concept closely aligned with early thyroid dysfunction. For

instance, *Ashwagandha* (*Withania somnifera*), a well-documented adaptogen, has demonstrated significant improvement in serum TSH, T3, and T4 levels in clinical settings. Its *rasayana* (rejuvenate) and *balya* (strength-promoting) actions help regulate the hypothalamic-pituitary-thyroid (HPT) axis, supporting metabolic functions naturally. The use of such a single-drug protocol not only simplifies treatment but also offers a safer, more targeted approach for patients in the early stages of thyroid hypo-regulation.

Objectives

To evaluate efficacy of *Shigru* (*Moringa oleifera* Linn.) *patra churna* tablet in the management of Subclinical Hypothyroidism.

Hypothesis:

- Null Hypothesis (H0) – *SHIGRU* (*Moringa oleifera* Linn.) *Patra choorna* tablet is not effective in management of subclinical hypothyroidism
- Alternate Hypothesis (H1) - *SHIGRU* (*Moringa oleifera* Linn.) *patra choorna* tablet is effective in management of subclinical hypothyroidism

2. MATERIALS AND METHODS

Trial design:

It was a single arm Open labeled Clinical Trial aimed at assessing the effect of *Shigru patra churna* tablet in Subclinical hypothyroidism and specially to assess effect over TSH. Patients attending the outpatient department of Specialty OPD No.3 of KLE Ayurveda Hospital, Belgavi, Karnataka, India were investigated for diagnosis of Subclinical Hypothyroidism. Patients having complaints of Gradual weight gain, Lethargy, Loss of energy,

Sleepiness, Decreased appetite, Dry skin, Hair loss, Depression, Forgetfulness, Menstrual disturbances, Infertility, Constipation, Periorbital puffiness, non-pitting edema, Exertional dyspnea were evaluated for the current clinical study and diagnosed with Sub-clinical Hypothyroidism as indicated by European Thyroid Association[11] and American Thyroid Association [12] guideline for Hypothyroidism. Thirty patients who met the inclusion criteria were included to the trial. It was an open labeled clinical trial. This study was designed as an open-label, exploratory pilot experiment to evaluate the first effects of the intervention on TSH levels, weight loss, and inch loss over a 42-day period.

The study received approval from the Institute's Institutional Ethics Committee (BMK/21/PG/DG/1, dated 18 August 2022) additionally the trial was registered in the Clinical Trial Registry of India (CTRI No: CTRI/2022/12/048317, on 20th December 2022). Before each patient was included in the clinical trial, their signed informed consent was obtained. Medicines were given for 42 days (i.e. 1 *mandala*) before food considering as *Rasayana Kala* (medicine supposed to prevent old age and prolong life). A comprehensive clinical research proforma that covers every aspect of taking a patient's history and collecting drugs, assessment, adverse events, if any, were recorded for analysis purpose. The recommended dietary do's and don'ts were explained to avoid dietary aberrations. The patient was advised to avoid use of any other drug for any ailment without consulting the treating physician.

Study Population:

Patients attending Specialty OPD No.3 of KLE Ayurveda Hospital, Belagavi & freshly diagnosed with Subclinical Hypothyroidism. Participants were included if they had been freshly diagnosed and not on any Anti-thyroid medication. Patients with Anti-thyroid medication, congenital hypothyroidism, patients undergone thyroid surgery, complications of CVS, infertility were excluded.

Sample size calculation:

In order to assess safety signals, efficacy trends, and practicality, a realistic sample size of 30 participants was selected due to its pilot status. Despite the predicted sample size of 160 persons to detect a 20% change in TSH with 90% power and $\alpha = 0.05$, the current sample was considered appropriate for generating preliminary data. The effect size estimates from this initial study will guide the design and power calculations of future, larger-scale randomized controlled trials. The study emphasizes the limitations of its statistical power and places more emphasis on the interpretative significance of visible patterns than on conclusive hypotheses.

Sample Size: 30 patients.

Study setting:

Specialty OPD of KLE Ayurveda Hospital, Shahapur. Intervention started from March 2023 to April 2024. Total duration of study was for 1 year 1 month.

Diagnostic criteria:

Patients coming with complaints of weight gain, hair-fall, edema, irregular menstrual cycle, generalized weakness were checked with hematological examination i.e. Thyroid profile. Patients who had TSH

level more than normal range but less than 10 mIU/L were included in the study.

Inclusion criteria:

- Patient with typical symptomatology of Hypothyroidism
- Age between 20 years to 60 years of either sex
- T3 & T4 within normal range
- Increased TSH value more than normal range but within 10 mIU/L,
- Who were not been diagnosed previously with Thyroid disorder
- Who are not on any anti-thyroid medication
- Patients willing to give written informed consent were included in above study with explaining all legal rights of the patient.

Exclusion criteria:

- Patients with TSH > 10mIU/L,
- Patients on Anti-thyroid medication
- Subjects with congenital hypothyroidism
- Patients undergone thyroid surgery
- Subject with complications of Hypothyroidism like cardiovascular disorders, infertility, Myxedema coma etc
- Patients suffering from major systemic illness and long term drug treatment
- Pregnant or lactating women were excluded from the above study.
- Patients who are not willing to give written informed consent were excluded.

On Adverse drug event patient was informed to contact chief investigator.

Withdrawal criteria:

- Non-compliance with study protocols or instructions provided by the Principal Investigator and/or study staff
- Occurrence of adverse events (AEs) or serious adverse events (SAEs)
- Determination by the Principal Investigator that continued participation may pose a risk to the participant's health or well-being
- Requirement for treatments or interventions not permitted within the study protocol
- Administrative or regulatory considerations

Medication and treatment plan:

Preparation of trial drug:

Trial drug i.e. *Shigru (Moringa oleifera* Linn.) patra was collected as per explained in classics. *Shigru patra* was collected in *Varsha ritu* (rainy season) according to *Acharya Sushruta*.^[13] collected drug is then dried and it's *churna* (powder) is prepared as per standard methods under supervision. Tablet in prepared out of *churna* is 500 mg weight. It is stored in air tight container in GMP certified KLE Ayurveda Pharmacy. Drug is kept in standard conditions in MRC, KLE Ayurveda Hospital, Belgavi.

PRIMARY AND SECONDARY OUTCOME OBJECTIVES-

The primary outcome was reduction in TSH values and an additional parameter was reduction in the body weight and waist circumference. Subjective parameters were *Keshapatana, Medovridhi, Shotha, Aniyamita-artava & Klama*. Patients have been screened for changes in subjective parameters on 0th day, 15th day,

30th day and 42nd day. For changes in objective parameters on baseline and on 43rd day.

Investigations:

Serum T3, serum.T4 and serum TSH was done on baseline and after completion of intervention i.e. on 43rd day. Serum T3 and T4 was done to evaluate the change in them, just to assess if patient is going into classical Hypothyroidism or Hyperthyroidism.

Intervention plan:

The intervention drug was provided either to the patient or the patient's attendants to be administered at home, as daily visits to the trial site were not feasible. 1st bottle of *Shigru patra churna* tablet was given on baseline day after enrollment in clinical trial. And 2nd bottle was given on 21st day after assessment of Subjective parameters and Adverse Drug Reaction if any. Each bottle contains total 84 tablets for 21 days. The patient's attendant is advised to maintain a diary to document each daily dose of medication, to prevent missed doses and promote adherence to the trial protocol.

Assessment criteria:

Following treatment completion, the study's outcomes were evaluated based on improvements in the patients' signs and symptoms as determined by Ayurvedic and modern criteria, as well as studies conducted both before and after the intervention in subjects after their demographic information had been previously recorded. For assessment objective as well as subjective parameters were compared i.e. Thyroid profile (T3,T4 and TSH), body weight and waist circumference and

parameters like *Keshapatana* (hairfall), *Medovridhhi* (increased fat), *Shotha* (oedema), *Aniyamita Artava* (irregular menstrual cycle) and *Klama* (fatigue) were evaluated.

Data analysis :

The data obtained from the research study underwent statistical analysis and was calculated according to the percentage of improvement in the parameters across all treated individuals. Statistical evaluations were carried out with Graph Pad Prism software. The data is presented as mean +/- standard error of mean for the group. Wilcoxon matched pairs signed rank test was used for within group data of qualitative data of Subjective parameters and student T-test for within group was used for quantitative data of hematological investigation and weight loss and waist circumference. Finally overall effect of therapy was evaluated.

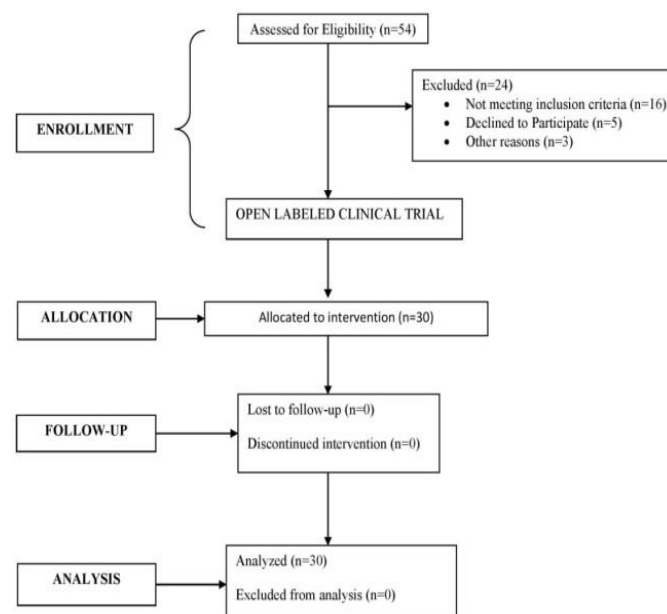
3. OBSERVATIONS AND RESULT:

In present study, total 30 patients were included. All patients completed the study without any adverse effect during and after the study. Most of the subjects were Female and most of the subjects were from 21 to 50 years age group, more patients population were from urban area and from Middle class family. The recruitment of patient was started on 29-03-2023 and ended on 05-01-2024.The demographic details of this study are mentioned in table no. 1

Table No.1 Showing the baseline demographic and clinical characteristics

Gender	Male	23.33 %
	Female	76.66 %
Age	20 – 30 years	16.66 %
	31 – 40 years	26.66 %
	41 – 50 years	33.33 %
	51 – 60 years	23.33 %
Occupation	Student	6.66 %
	Desk work	33.33 %
	House maker	50 %
	Field work	10 %
Habitat	Urban	83.33 %
	Rural	16.66 %
Status	Lower class	26.66 %
	Middle class	3.33 %
	Upper class	70 %
BMI	Underweight	3.33 %
	Normal weight	26.66 %
	Overweight	40 %
	Class I Obese	26.66 %
	Class II Obese	3.33 %
<i>Keshapatana</i>	Present	90%
	Absent	10%
<i>Medovriddhi</i>	Present	70 %
	Absent	30 %
<i>Shotha</i>	Present	46.66%
	Absent	53.34%
<i>Aniyamita artava</i>	Present	33.33%
	Absent	66.67%
<i>Klama</i>	Present	96.66%
	Absent	3.34%

Image No. 1 Showing Flow of Participants



All of them have reduced symptoms periodically, where 27 out of 30 patients showed periodically reduced symptom of *Keshapatana* (hairfall) and only 5 patients remained with same symptom of hair fall ($P < 0.0001$), Cohen's $d = 2.13$, indicating a large effect, Mean percentage reduction in hairfall scores = 81.48%, suggesting clinically meaningful improvement. (Fig.no.1) (Table no.2),

Fig. no.1 Showing change in Keshapatana (Hairfall)

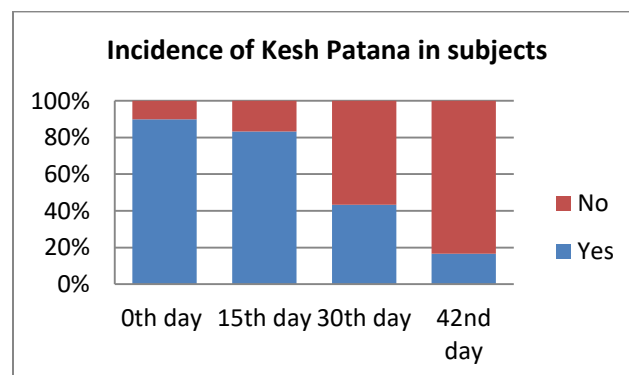


Table No.2 Showing the statistics of *Kesha-patana* parameter

Mean		Std. Deviation		P value	Summary	Cohen,s d	Mean reduction
BT	AT	BT	AT	<0.0001	Highly significant	2.13	81.48%
0.9	0.1667	0.3051	0.3790				

(BT- Before treatment, AT-After Treatment)

Shotha was present in 14 patients and at last every patient was relieved of *Shotha lakshana* (P<0004), calculation of Cohen’s d = 1.14 which suggests large and meaningful difference, 92.83% improvement, clear & real-world impact. (Fig.No.2) & (Table no.3);

Fig.no.2 Showing periodically changes in *Shotha*

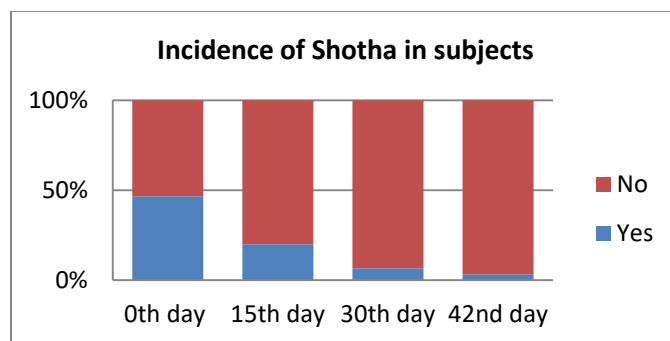


Table no.3 Showing the statistics of *Shotha* parameter

Mean		Std. Deviation		P value	Summary	Cohen’s d	Mean Percentage
BT	AT	BT	AT	<0.0004	Highly significant	1.14	92.83%
0.4667	0.0333	0.5074	0.1826				

(BT- Before treatment, AT-After Treatment)

10 patients given complaint of *Artava Aniyamitata* (irregular menstrual cycle), all of them had got their Menstrual cycle after 28 days without pain and clots during cycle (P<0.0019), the mean reduction of 100%

and a Cohen’s d of 0.98 was calculated which suggest a large and clinically meaningful impact of the treatment (Table no.4) (Fig.No.3);

Table no.4 Showing statistical analysis of *Artava aniyamitata* parameter

Mean		Std. Deviation		P value	Summary	Cohen’s d	Mean reduction
BT	AT	BT	AT	<0.0019	Significant	0.98	100%
0.3333	0	0.4795	0				

(BT- Before treatment, AT-After Treatment)

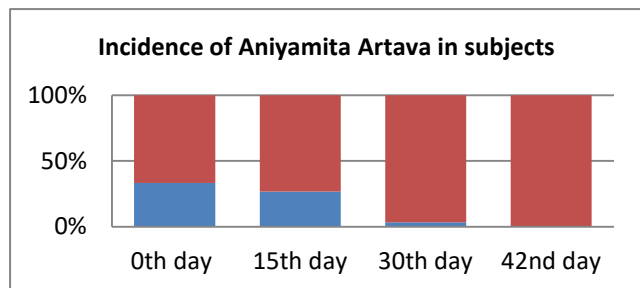


Fig. No.3 Periodical Change in *Artava Aniyamitata*

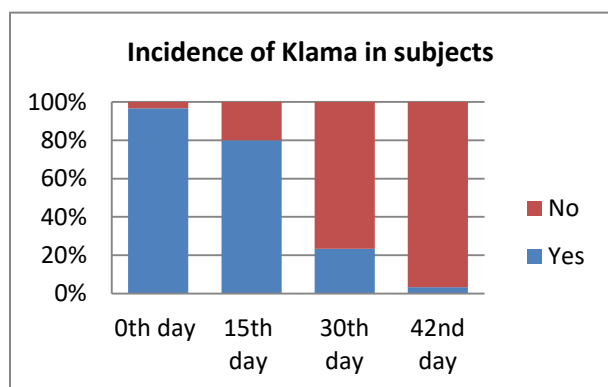
29 patients had complaint of *Klama* after intervention all of them relieved from *klama* ($P < 0.0001$), Cohen’s d of 5.11, indicating a extremely large effect size, and a mean

percentage reduction of 96.59 % in *klama* symptoms. (Fig. No.4) (Table no.5) ;

Table no.5 Showing statistical changes in *Klama* parameter

Mean		Std. Deviation		P value	Summary	Cohen’s d	Mean reduction
BT	AT	BT	AT				
0.9667	0.033	0.1826	0.1826	<0.0001	Highly Significant	5.11	96.59%

Fig.no.4 Showing periodical changes in *Klama* parameter



21 out of 30 patients complained of *Medovriddhi* on baseline day, nobody had *Medovriddhi lakshana* on last day ($P < 0.0001$), Cohen’s d of 2.15, indicating a extremely large effect size, and a mean percentage

reduction of 100 % in *medovriddhi* symptoms (Fig.No.5) (Table no.6)

Fig.no.5 Showing periodical changes in *Medovriddhi lakshana*

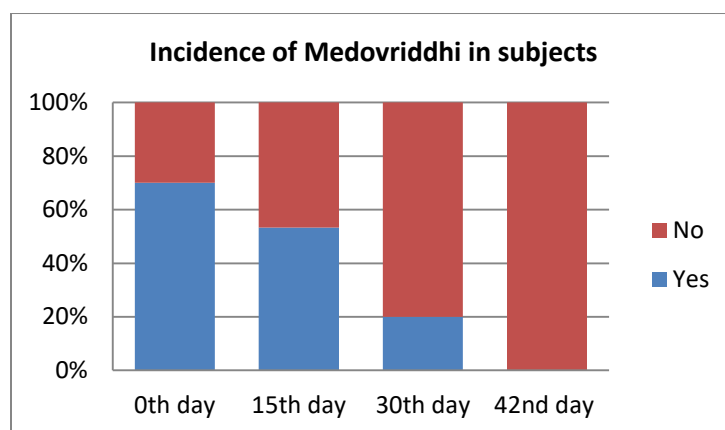
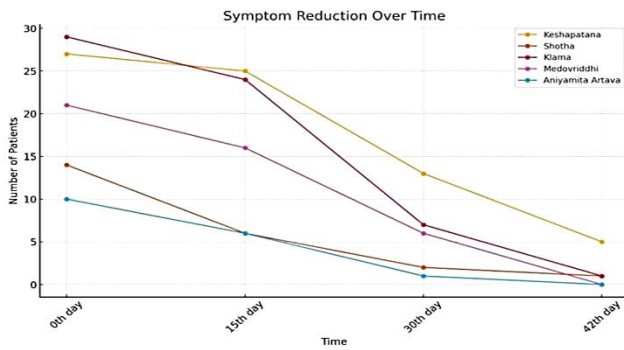


Table no.6 Showing statistical changes in *Medovriddhi* parameter

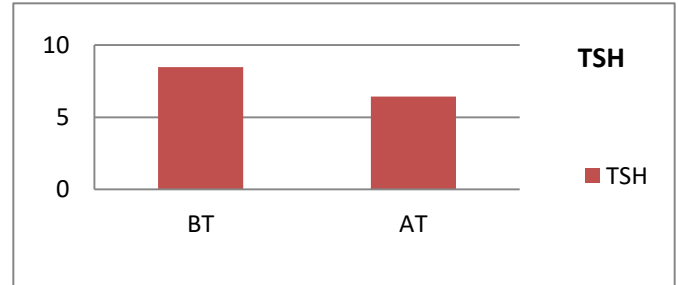
Mean		Std. Deviation		P value	Summary	Coden’s d	Mean reduction
BT	AT	BT	AT				
0.7	0	0.46	0	<0.0001	Highly significant	2.15	100%

Image no.2 showing periodical changes in the five key subjective symptoms (*Keshapatana, Shotha, Klama, Medovriddhi, and Aniyamita Artava*)



say that above intervention is effective in the reduction of increased TSH values (Table no.7) (Fig. No.6)

Fig.no.6 Showing change in TSH values



TSH showed highly significant value ($P < 0.0003$) which

Table no.7 Showing Statistical changes in TSH value

P value	T value	Mean of difference	Mean		Std deviation		Summary	Coden's d	Mean reduction
			BT	AT	BT	AT			
<0.0003	4.096	2.050	8.485	6.435	3.010	3.876	Highly significant	0.59	24.15%

Though study was not focusing on value of T3 but it also showed the significant result ($P < 0.0142$) in (Table no.8)

Table no.8 Showing the statistical changes in T3

P value	T value	Mean of difference	Mean		Std deviation		Summary	Coden's d	Mean reduction
			BT	AT	BT	AT			
0.0142	2.609	0.947	2.951	2.004	1.515	1.837	Significant	0.56	32.09%

where values of T4 remain unchanged ($P < 0.2374$) which is not significant. [Fig.No.8] (Table no.9)

Table no.9 Shows statistical changes in T4 (before and after intervention)

P value	T value	Mean of difference	Mean		Std. deviation		Summary	Coden's d	Mean reduction
			BT	AT	BT	AT			
0.2374	1.206	0.4907	8.119	7.628	2.146	1.868	Not Significant	0.24	6.25%

Weight loss parameter showed highly significant result ($P < 0.0001$) also waist circumference showed same result that of TSH & weight loss ($P < 0.0001$). [Fig.No.7] [table no. 10]

Fig.no.7 Showing changes in weight and waist circumference

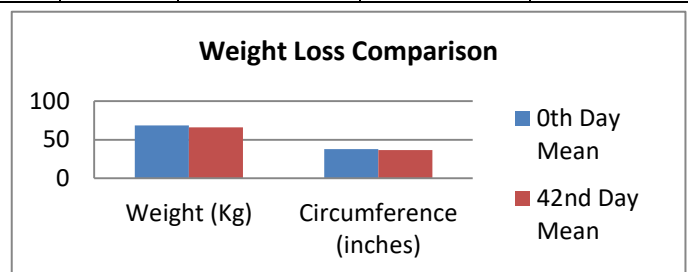


Table no.10 Showing statistical change in Objective parameters

Parameter	0th Day mean (SD)	42nd Day Mean (SD)	Paired sample (t-value)	P-value	Summary	Coden's d	Mean reduction
Weight (Kg)	68.46 (11.20)	66.01 (10.45)	6.054	<0.0001	Highly significance	1.31	90.58%
Circumference (Inches)	37.83 (4.49)	36.60 (3.82)	4.597	<0.0001		0.30	3.25%

(SD-Standard deviation)

4. DISCUSSION

Subclinical Hypothyroidism is a disorder which affects multiple system one or other way. Earlier manifestation goes un-noticed. When the onset of symptoms disrupts their lifestyle they start noticing the bodily changes. *Santarpanjanya ahara-vihara* (nourishing food and activities) leads to *Agnimandya* causing improper *Dhatu* formation which results in symptoms like *Aruchi* (anorexia), *Atinidra* (excess sleep), *Bhara vridhhi*, *Keshapatana*, irregular menstrual cycle and reduction in appetite. Similar symptomatology of Subclinical Hypothyroidism is seen in *Rasa pradoshajavikara* or *Mandagni janita vikara*.

The symptoms of Subclinical Hypothyroidism mainly shows *Kapha dosha vridhhi* (increase in kapha dosha), *Medo Vridhhi* and *Tamoguna vridhhi*. *Kapha dosha vridhhi* shows symptoms like lethargy, less menstrual bleeding, somnolence, slowing of physical as well as mental activities, edema, intolerance to cold, weight gain, periorbital edema and puffy face, exertional dyspnea, absence of sweating despite of heavy activities etc.

Tamoguna vridhhi symptoms are like lethargy, somnolence, slowing of mental activities and depression.

One of the synonyms of *Shigru* is *Mochaka* which means it eradicates so many diseases. *Shigru* is also said as to be Powerhouse of nutrients. *Mandagni* related symptoms in SCH are taken care by *Deepana – Pachana* (digestion and metabolism enhancing) property of *Shigru* and reduces further progress of disease. *Katu rasa* does *Agni Deepana* and *shoshana* (drying up) action when administered on empty stomach. *Katu rasa* have property of *bhuktam shoshayati* and *karshayati* (reduces fat) as well as *Tikta rasa* has *Kleda-Meda shoshana* and *karshayati* property which helps in *Medovridhhi lakshana* in SCH. *Shigru* also have *Katu rasa & Ushna veerya*, also *katu rasa* has *Shonita-sanghat-bhinnati* property which will helps *insamprapti* of *Avaranajanita artavaaniyamitata* & for *samprapti vighatana* in *Medovahasroto dusti* (disease of medovaha channel).

Shotha is one the symptom seen in SCH, which is *Kapha-Vataja* disorder ;*Shigru* is *vata-kapha shamak*, it's *Ushna*

veerya, *Laghu-Ruksha-Tikshna guna* & *Srotoshodhak* (purifies channels) *karma* tackles the symptom. Symptom like somnolence is due to *Kapha* and *Tamo gunavridhhi* (quality of darkness), *Shigru* is *teekshna* and *Katu* in *rasa* which acts against it and resolve it.

Shigru contains ascorbic acid which is essential to absorb Iron which is necessary for promoting hair growth and reduces hair loss. It also contains Quercetin has antioxidant & anti-inflammatory effect, it helps in inhibition of adipogenesis.

While checking thyroid function test pre and post, there was no extreme change in the value of T4. Although no significant changes were observed in serum T4 levels, participants reported consistent improvement in key subjective symptoms. This may reflect enhanced peripheral sensitivity to thyroid hormone, improved T4 to T3 conversion, or metabolic effects of the therapy that do not directly influence circulating T4. Additionally, the relatively short study duration and normal baseline T4 values could have limited measurable hormonal change despite clinical benefit.

Experimental studies have demonstrated that effects involve the inhibition of thyroid hormone synthesis and the impairment of the iodine concentrating mechanism in the thyroid gland. This is attributed to the presence of cyanogenic glucosides, glucosinolates, thiocyanate, and polyphenols in these plant foods. These compounds are thought to inhibit the activities of thyroid hormone synthesizing enzymes, such as TPO, Na⁺-K⁺-ATPase, and deiodinase I, leading to altered thyroid hormone profiles and morphological changes in the thyroid gland.

Additionally, the study suggests that the presence of excess thiocyanate and polyphenols may contribute to the reduced synthesis of thyroid hormones, supporting the plausibility of this pathway.[14]

Overall effect of the intervention:

The interpretation of results aligns with the observed data, showing a significant decrease in the signs and symptoms of subclinical hypothyroidism (SCH). Statistically significant improvements, particularly in TSH levels, *Medovridhhi*, *Klama* and *Keshapatana*, support the overall efficacy of the therapy. No adverse effects were reported during the trial, indicating a favorable benefit-harm profile. These findings are consistent with existing literature suggesting that holistic interventions may positively influence thyroid function and associated symptoms.

Limitation of Study :

There was difficulty in finding new cases where patient is not on any antithyroid medications. Single group was used, study may have been stronger if comparative group was made. Limited number of participants was there due to fear of not getting new cases of disease. Non-blinding increases risk of bias in symptom reporting and outcome assessment, especially for subjective measures. The absence of randomization limits the study's ability to account for confounding variables. In randomized trials, such factors are balanced across groups, strengthening causal inference. In contrast, this single-arm design cannot exclude the possibility that observed improvements arose from non-intervention-related causes such as natural disease progression,

placebo response, or lifestyle changes. Limited participants reduce statistical power. Small sample size increases the chance of Type II errors (missing real effects), and limits generalizability of results to a broader population. 42-day period may not be long enough to assess long-term efficacy or side effects. While the findings suggest potential benefit, the study's single-arm design and limited sample size preclude definitive conclusions. Further randomized, controlled trials with larger cohorts are warranted to validate these results.

Generalisability of study findings:

Due to the small sample size of 30 participants, the generalisability of the study findings may be limited. Larger studies are needed to confirm the applicability of these results to broader populations.

5. CONCLUSION

Shigru (Moringa oleifera Linn.) *patra churna* tablet is effective in above study without any Adverse Drug Reaction during and after the intervention. It can be one of the drug of choice in case of Subclinical Hypothyroidism depending on physician choice of drug. While the findings of this single-arm study suggest promising clinical improvements in key subjective symptoms associated with hypothyroidism, the absence of a control group and the limited sample size restrict the ability to draw definitive causal inferences. The lack of significant change in T4 levels, despite symptom relief, further highlights the complexity of thyroid regulation and the potential for non-hormonal pathways to influence patient well-being.

To establish the efficacy and mechanism of the therapeutic intervention more conclusively, future research should focus on randomized controlled trials (RCTs) with larger and more diverse populations. Such studies would help control for placebo effects, better account for confounding variables, and enhance the generalizability and statistical power of the findings. Validation through RCTs would also enable more accurate comparisons with standard treatments and provide stronger evidence for clinical or integrative use.

Scope of Further Study:

Different parts of *Shigru* can be studied for their effect on Hypothyroidism, Dosage form can be changed & its effect on thyroid function can be assessed, most important is Comparative Randomized trial can be done.

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Author Details:

¹Final year PG Scholar,

^{2*} Professor &HOD, Dept of Dravyaguna,

Shri.B.M.Kankanwadi Ayurveda Mahavidyalaya,Shahapur

Author contributions:

Conceptualization and Clinical Management: All authors

Data Collection and Literature Review: Dr. Shubham K

Writing – Original Draft: Dr. Shubham K

Review and Editing: All authors

Final Approval of the Manuscript: All authors

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