Original Article

Efficacy of *Vyoshadi Guggulu* and *Shadushana Churna* in the management of subclinical hypothyroidism: An open labelled randomized comparative pilot clinical trial

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Abstract

Background: Subclinical hypothyroidism (SCH) is defined as a mildly reduced function of the thyroid gland having elevated serum thyroid-stimulating hormone (TSH) level and normal concentrations of free tri-iodothyronine (FT3), free tetra-iodothyronine (FT4), T3 and T4. It occurs due to *"Agnimandya"* (low metabolic activity) at the systemic and cellular level. *Vyoshadi Guggulu* and *Shadushana Churna* having its effect on *Agni* (a root cause of SCH) are expected to prevent overt hypothyroidism and revert subclinical stage to euthyroid. **Aim:** This study was planned to evaluate and compare the efficacy of *Vyoshadi Guggulu* and *Shadushana Churna* in the management of *Dhatvagnimandya* with special reference to sub-clinical hypothyroidism (SCH). **Materials and methods:** Patients having serum TSH levels between 5 and 10 mIU/L and normal T3 and T4 values were diagnosed as SCH. A total of 30 patients were registered and randomly divided into two groups. In group A, patients were treated with *Vyoshadi Guggulu* (6 g), while in group B with *Shadushana Churna* (3 g) twice a day after lunch and dinner for 60 days. The assessment was done through changes in baseline and after treatment values of serum TSH level. Outcomes of the trial were analyzed using SigmaStat 4.0 version (trial) software. Student's paired *t*-test was used for within-group assessment, while unpaired *t*-test was used for intergroup comparison of the normally distributed parametric data. **Observations and Results:** Ten patients in group A and 11 in group B could complete the course of treatment. The findings revealed that therapy in group A and B showed decrease of 16.61% ($P = 0.0494$) and 26.29% ($P = 0.0140$) in serum TSH, respectively, 1.80% ($P = 0.025$) and 1.36% ($P = 0.019$) decrease in body mass index (BMI), respectively. The decrease in TSH and BMI was statistically significant in each group. In comparison, the decrease in serum TSH ($P = 0.384$) and BMI ($P = 0.677$) was statistically insignificant. **Conclusions:** *Vyoshadi Guggulu* and *Shadushana Churna* are statistically equally effective to reduce serum TSH and BMI in the management of SCH.

Keywords: *Agni, Dhatvagnimandya, Shadushana Churna*, subclinical hypothyroidism, *Vyoshadi Guggulu*

Introduction

Subclinical hypothyroidism (SCH) is defined as a mildly reduced function of the thyroid gland with either minimal symptoms or no symptoms of hypothyroidism having an elevated serum thyroid-stimulating hormone (TSH) level and normal concentrations of free T3 (FT3), free T4 (FT4), T3, and T4.[1,2] A large cross-sectional study confirmed that the participants with SCH reported more symptoms than euthyroid individuals, but fewer symptoms than overtly hypothyroid participants. The study could not distinguish between untreated SCH and under treated overt hypothyroidism.[3]

SCH or mild thyroid failure is more prevalent in recent years and is causing major controversies concerning management and treatment. In the Wickham study, an extensive population-based survey, the prevalence of SCH is 7.5% in women and 2.8% in men.[4] The highest prevalence (up to 16%) was found in elderly women over 60 years of age.[5] It is more prominent in females rather than males.[6]

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Based on Ayurvedic principles, after understand the pathology of SCH as the *"Agnimandya"* (low metabolic activity) at the systemic and cellular level which can be understood as a decreased caloric expenditure (hypometabolism) in modern terminology. *Agnimandya* at any level due to *Kaphakara Nidana* (*Kapha* increasing causative factors) results in increased *Dhatugata Mala Sanchaya* (accumulation of excretory products at a cellular level), resulting in *Srotorodha* (blockage of microchannels) causing compromised *Dhatu – Sara* (the essence of body tissues) leading to both physical and mental features in SCH, as swelling, anemia, constipation, cold intolerance, etc. This *Agnimandya* results in the formation of abnormal *Rasa Dhatu* (semi-digested food), i.e., *Ama*.[7] *Ama Lakshana* and the symptoms seen in SCH are similar. The line of treatment of *Ama Dosha* revolves around *Pachana* (digestion of *Ama)* then *Deepana* (digestive stimulant) and lastly *Shodhana* (detoxification) after *Snehana* (medicated oiling therapy) and *Swedana Karma* (steam sudation).

Vyoshadi Guggulu and *Shadushana Churna* have been selected to manage SCH. These formulations are having *Deepana* (digestive stimulant), *Paachana* (digest and metabolize the food), *Srotoshodhaka* (clears microchannels of the body), *Medohara* (decreases fat in the body), and *Lekhana* (scraping of fat and lipid contents) properties, administration of these drugs improves functions of *Agni*. *Agnimandhya* (poor digestion and metabolic activity) is the prime cause of SCH. *Medavaha Srotosa* and *Rasavaha Srotasa Dushti* (vitiation of microchannels of the body carrying lipid substances and nutrients) is mainly observed in the condition of SCH. Hence, the drugs having *Deepana*, *Pachana* as well as *Lekhana* actions and having *Ruksha* (dry) and *Ushna* (hot) *Guna* (property) are expected to correct the underlying pathology of the diseases and improve the condition. By their contents, *Vyoshadi Guggulu* and *Shadushana Churna* possess *Agnideepana* (metabolic stimulant) and weight-reducing properties. No research work has been carried out to see the effect of these trial drugs on SCH. Hence, these formulations were selected to assess and compare their efficacy in the management of SCH. The trial was planned to answer the research question that which trial drug is more effective to reduce the serum TSH level and what is their effect on body mass index (BMI).

Aims and objective

1. To evaluate and compare the efficacy of *Vyoshadi Guggulu* and *Shadushana Churna* in the management of *Dhatvagnimandya* w. s. r. to sub-clinical hypothyroidism
2. To assess the safety of *Vyoshadi Guggulu* and *Shadushana Churna* in the management of *Dhatvagnimandya* w. s. r. to SCH.

Objectives

Primary objective

Reduction in serum TSH level (Time duration 60 days, assessment on the base of thyroid profile test).

Secondary objectives

1. Decrease of BMI (Time duration 60 days, assessment based on changes in BMI)
2. Safety of trial drugs (Time duration 60 days, assessment on the base of liver and renal function tests, and adverse drug reactions reported by patients if any).

Materials and methods

Selection of the patients

Patients who reported to the outpatient department of the Kayachikitsa , National Institute of Ayurveda, Jaipur, were investigated for diagnosis of SCH. Patients having any one or more conditions like family history of hypothyroidism, increasing body weight, excessive appetite, hair fall, oligomenorrhea, dry skin, fatigue, hoarseness of voice, peripheral edema, cold sensitivity, chronic constipation, or previously diagnosed case of SCH were screened for the present clinical trial. Patients were diagnosed based on thyroid profile. Patient having their serum TSH level between 5 and 10 mlU/L and normal level of serum T_3 and T_4 (normal reference range: T_3: 1–2 ng/mL and T_4: 5–12 mg/dL) were diagnosed as cases of SCH. A total of 30 patients fulfilling the inclusion criteria were included in the study. Selected patients were randomly divided into two groups, irrespective of their age, sex and religion, by the computer-generated randomization method. Allocation concealment was done by SNOSE (Sequentially Numbered Opaque Sealed Envelope) method. The study was approved by the Institutional Ethics Committee with No. IEC/ACA/2018/9 in the deliberation held on May 9–10, 2018, and the trial was also registered in the clinical trial registry of India (CTRI No: CTRI/2019/05/018988) Prior informed written consent was obtained from each patient before including in the study. A detailed clinical research pro forma, incorporating all the points of history taking, physical examination, and assessment of the treatment, was maintained for record and analysis purposes.

Inclusion criteria

A subject fulfilling the following criteria were eligible for inclusion in this study:

1. Patients age between 18 and 60 years of either sex
2. Newly/previously diagnosed patients having TSH level 5–10 mlU/L
3. Patients having symptoms any one or more conditions like family history of hypothyroidism, increasing body weight, excessive appetite, hair fall, oligomenorrhea, dry skin, fatigue, hoarseness of voice, peripheral edema, cold sensitivity, chronic constipation
4. Patients willing to participate in the study.

Exclusion criteria

1. Patients below 18 years and above 60 years of age
2. TSH level more than 10 mlU/L or < 5 mlU/L
3. Patients under allopathic treatment for subclinical or clinical hypothyroidism
4. Patients suffering from any other systemic illness viz. diabetes, hypertension, liver disorders, etc

5. Pregnant and lactating patients
6. Patients undergoing treatment for any other systemic illness
7. Patients participated in any clinical trial within the last 6 months.

Trial drug details

Vyoshadi Guggulu

Vyoshadi Guggulu is a polyherbal formulation mentioned in *Brihat Nighantu Ratanakar*. The ingredients of *Vyoshadi Guggulu* are mentioned in Table 1.[8]

Method of preparation of *Vyoshadi Guggulu*

The herbal ingredients of *Vyoshadi Guggulu* such as *Shunthi, Maricha, Pippali, Haritaki, Vibhitaka, Amalaki* and *Kanchanaara* were purchased from local market and authenticated by the purchasing and authentication committee of raw drugs of the pharmacy. These drugs were taken according to the mentioned ratio [Table 1] and made into a fine powder and passed from 80# sieve. The purified *Guggulu* powder and honey (purchased from local market) added to the herbal powder as per the quantity mentioned. Then, all the mixtures were amalgamated well and finally, semisolid *Vyoshadi Guggulu* was prepared in *Vati* form.

This drug was prepared in the GMP-certified pharmacy of the Institute.

Shadushana Churna

Shadushana Churna is a polyherbal formulation mentioned in *Bhava Prakash Nighantu Haritakyadi Varga*. The ingredients of *Shadushana Churna* are mentioned in Table 2.[9]

Table 1: The ingredients of *Vyoshadi Guggulu*

Drugs	Botanical name	Part used	Quantity
Shunthi	*Z. officinale* Rosc.	Rhizome	2 part
Maricha	*P. longum* Linn.	Fruit	2 part
Pippali	*P. nigrum* Linn.	Fruit	2 part
Haritaki	*T. chebula* Retz.	Pulp	1 part
Vibhitaka	*T. bellirica* Roxb.	Pulp	1 part
Amalaki	*E. officinalis* Gaertn.	Pulp	1 part
Kanchanaara	*B. variegata* Linn.	Bark	12 part
Guggulu	*C. mukul* Engl.	Gum	21 part
Madhu	Honey	-	100 part

Z. officinale: Zingiber officinale, P. longum: Piper longum, P. nigrum: Piper nigrum, T. chebula: Terminalia chebula, T. bellirica: Terminalia bellirica, E. officinalis: Emblica officinalis, B. variegata: Bauhinia variegata, C. mukul: Commiphora mukul

Table 2: The ingredients of *Shadushana Churna*

Drugs	Botanical name	Part used	Quantity
Pippali	*P. nigrum* Linn.	Fruit	1 part
Pippalimoola	*P. nigrum* Linn.	Root	1 part
Chavya	*P. retrofractum* Vahl.	Stem	1 part
Chitraka	*P. zeylanica* Linn.	Root	1 part
Shunthi	*Z. officinale* Rosc.	Rhizome	1 part
Maricha	*P. nigrum* Linn.	Fruit	1 part

P. nigrum: Piper nigrum, P. retrofractum: Piper retrofractum, P. zeylanica: Plumbago zeylanica, Z. officinale: Zingiber officinale

Method of preparation of *Shadushana Churna*

Ingredients of *Shadushana Churna* [Table 2] were taken in equal quantity and made into fine powder. The contents of *Shadushana Churna* were purchased from local market authenticated by the purchasing and authentication committee of raw drugs of the GMP-certified pharmacy. It was prepared in pharmacy of the Institute as per the classical description of *Churna Kalpana* mentioned in *Churna* preparing chapter of Sharangdhar Samhita.[10]

Grouping and posology

Patients in group A were treated with *Vyoshadi Guggulu Vati* 6 g twice a day after lunch and dinner orally with *Anupana* (vehicle) of lukewarm water for 60 days. Patients in group B were treated with *Shadushana Churna* 3 g twice a day after lunch and dinner orally with *Anupana* (vehicle) of lukewarm water for 60 days.

Assessment criteria

The primary outcome was assessed based on the change in baseline and after treatment (After 60 days) value of serum TSH. The effect of trial drugs on BMI was assessed based on change in baseline and after treatment value of BMI. BMI was calculated by dividing weight (in kg) by square of height in meter. Safety of trials drugs was assessed through liver function test (serum glutamic oxaloacetic transaminase [SGOT], serum glutamic pyruvic transaminase [SGPT]), and renal function test (serum creatinine and blood urea).

Statistical methods

Sigma state 4.0 version, manufactured by Informer Technologies, Inc. was used to find the standard deviation, standard error, *t*-value (Student's paired and unpaired *t*-test calculated value), and *P* (probability) values. Student's paired *t*-test was used to assess the level of significance for changes in baseline and after treatment values for objective parameters. Unpaired *t*-test was used to assess the level of significance between two groups for objective parameters. The obtained results were interpreted as:

- Not significant: $P > 0.05$
- Significant: $P < 0.05$
- Highly significant: $P < 0.01$, $P < 0.001$, $P < 0.0001$.

Observation

Patients for the present clinical trial were registered between the periods of June 2019 and February 2020. After 6 months of the clinical study, registration of the patients was closed having to submit the thesis work to the institute being a part of fulfillment for postgraduation degree. A total of 30 patients were registered for the present study and were randomly divided into two groups to evaluate comparative the efficacy of *Vyoshadi Guggulu* and *Shadushana Churna* in the management of *Dhatvagnimandya* w. s. r to SCH. Twenty-one patients completed the treatment successfully. In this trial, 15 patients in each group were allocated to the intervention of group A and group B. Ten patients in group A and 11 patients in group B could complete the course of treatment, while five

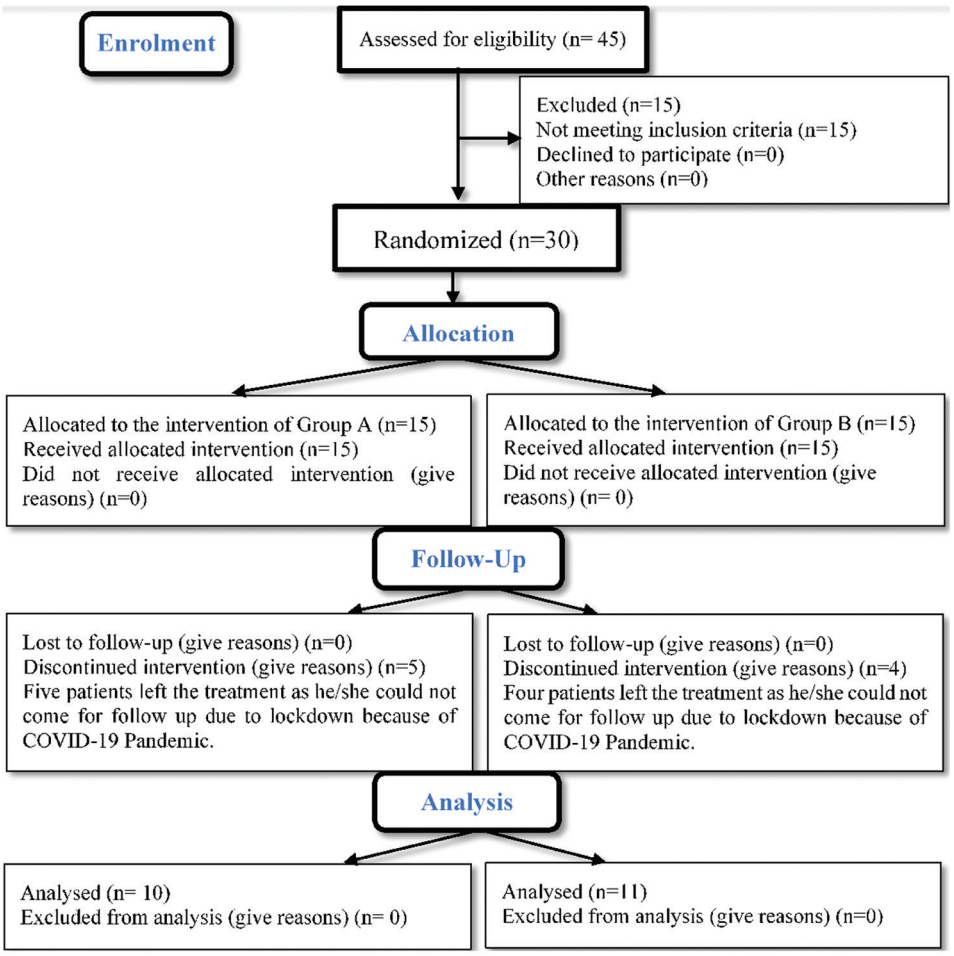

Figure 1: Flow chart: Consort flow diagram

patients in group A and four patients in group B could not come for follow-up due to lockdown because of COVID-19 pandemic [Figure 1].

In the present study, a maximum of 36.67% of patients were in the age group 31–40 years, 86.67% of the patients were female, 76.67% of patients from the Hindu community, 80% were married, 36.67% of patients were found to have graduate educational status, 60% of patients were observed to be of middle socioeconomic status, the maximum number of patients (56.67%) were housewives, 66.67% of patients were taking *Madhura Rasa* dominant diet, 63.33% of patients were vegetarian, 66.67% of patients were from the urban area, 60% of patients had a history of *Mandagni* (poor digestion and metabolic activities), 56.67% of patients had regular bowel habit, 60% of patients had normal sleep and 36.67% of female patients had a regular menstrual cycle.

Results

In the present clinical study, serum TSH was decreased by 16.61% and 26.29%, respectively, in group A and group B, which was statistically significant ($P < 0.05$). Serum T_3 and serum T_4 were within normal limits before and after treatment in all the patients in both the groups [Table 3]. On applying the unpaired *t*-test, the difference of decrease in serum TSH in group A and group B was statistically insignificant [Table 4].

The baseline average weight of patients in group A and group B was 63.70 kg and 67.36 kg, respectively. Weight was decreased by 1.57% and 1.35%, respectively, in group A and group B, which was statically significant ($P < 0.05$). The baseline BMI of patients in group A and group B was 23.86 and 25.49 km/m^2, respectively. BMI was decreased by 1.80% and 1.36%, respectively, in group A and group B, which was statically significant ($P < 0.05$). The vitals such as pulse and systolic and diastolic blood pressure were normal in all the patients in both the groups before and after treatment [Table 5]. On applying the unpaired *t*-test, the difference of decrease in weight and BMI in group A and group B was statistically insignificant [Table 6].

Liver function parameters (SGOT and SGPT) and renal function parameters (blood urea and serum creatinine) were within normal limits before and after treatment. No adverse drug reaction was observed in any groups throughout the study period [Table 7].

Table 3: Effect of therapy on thyroid function test (paired *t*-test)

Variable	*N*	Group	Mean		Mean difference	Percentage relief	SD±	SE±	*t*	*P*	Results
			BT	AT							
Serum T_3 (ng/mL)	10	A	1.018	0.940	0.078	7.66↓	0.128	0.0405	1.924	>0.05 (0.086)	NS
	11	B	1.14	1.06	0.08	7.40↓	0.130	0.0393	2.011	>0.05 (0.072)	NS
Serum T_4 (µg/dL	10	A	7.917	6.781	1.048	14.35↓	1.282	0.405	2.584	<0.05 (0.029)	S
	11	B	7.745	7.580	0.16	2.12↓	0.417	0.126	1.308	>0.05 (0.220)	NS
Serum TSH (µIU/mL)	10	A	6.961	5.805	1.156	16.61↓	1.611	0.509	2.270	<0.05 (0.0494)	S
	11	B	7.195	5.304	1.892	26.29↓	2.111	0.637	2.972	<0.05 (0.0140)	S

n: Total number of patients, ↓: Decrease, S: Significant, NS: Nonsignificant, SD: Standard deviation, SE: Standard error, BT: Before treatment, AT: After treatment, *P*: Probability value, TSH: Thyroid-stimulating hormone, T_3: Triiodothyronine, T_4: Tetraiodothyronine

Table 4: The comparative effect of both the interventions on thyroid profile (unpaired *t*-test)

Variable	*n*	Group	Difference mean	SD±	SE±	*t*	*P*	Results
Serum TSH (xIU/mL)	10	A	1.156	1.611	0.509	−0.891	0.384	NS
	11	B	1.892	2.111	0.637			
Serum T_3 (ng/mL)	10	A	0.0780	0.128	0.0405	−0.118	0.907	NS
	11	B	0.0845	0.126	0.0380			
Serum T_4 (µg/dL)	10	A	1.136	1.184	0.374	−0.997	0.331	NS
	11	B	1.892	2.111	0.637			

n: Total number of patients, NS: Nonsignificant, SD: Standard deviation, SE: Standard error, *P*: Probability value, T_3: Triiodothyronine, T_4: Tetraiodothyronine

Table 5: The effect of therapy on vitals, weight, and body mass index (paired *t*-test)

Variable	*n*	Group	Mean		Mean difference	Percentage relief	SD±	SE±	*t*	*P*	Results
			BT	AT							
Pulse rate	10	A	70.3	70.9	−0.6	−0.85↑	1.955	0.618	−0.970	>0.05 (0.357)	NS
	11	B	70.18	69.91	0.27	0.39↓	2.533	0.764	0.357	>0.05 (0.728)	NS
Blood pressure (systolic) mmHg	10	A	117	117	0	0.00↓	6.667	2.108	0.000	>0.05 (1.000)	NS
	11	B	118.18	116.36	1.82	1.54↓	4.045	1.220	1.491	>0.05 (0.167)	NS
Blood pressure (diastolic) mmHg	10	A	76	79	−3	−3.95↑	4.830	1.528	−1.964	>0.05 (0.081)	NS
	11	B	79.09	77.27	1.82	2.30↓	4.045	1.220	1.491	>0.05 (0.167)	NS
Weight (kg)	10	A	63.7	62.7	1	1.57↓	1.054	0.333	3.000	<0.05 (0.015)	S
	11	B	67.36	66.45	0.91	1.35↓	1.044	0.315	2.887	<0.05 (0.016)	S
BMI (kg/m^2)	10	A	23.86	23.43	0.43	1.80↓	0.506	0.160	2.689	<0.05 (0.025)	S
	11	B	25.49	25.14	0.35	1.36↓	0.408	0.123	2.806	<0.05 (0.019)	S

n: Total number of patients, ↓: Decrease, ↑: Increase, S: Significant, NS: Nonsignificant, SD: Standard deviation, SE: Standard error, BT: Before treatment, AT: After treatment, *P*: Probability value, BMI: Body mass index

Discussion

The trial drugs *Shadushana Churna* and *Vyoshadi Guggulu* are classical drugs and the doses mentioned in the classics for these drugs are 6 g and 12 g, respectively. Both the trial drugs, having *Ushna* and *Tikshana* (hot and fast-acting) properties, induce a burning sensation in the stomach if given an empty stomach. For the better adherence of the trial patients, drugs were given after lunch and dinner with lukewarm water for prompt assimilation of the drug without any untoward effect.

In the present study among 30 patients, the maximum number of patients (36.67%) belonged to the 31–40 years age group. This result showed that the maximum prevalence of SCH is in adults. SCH can start at any age, but the risk increases with age. SCH also increases vascular risk in all age groups but more significantly in the older age group.[11] A maximum of 86.67% of females was found to be affected by the ailment, it may be due to the effect of estrogen hormone.[12]

Some patients with SCH may experience symptoms associated with the disease, while some remain asymptomatic. Few studies also suggested its link to overt hypothyroidism and long-term complications like high risk of coronary artery diseases. The risk for the progress of the disease to overt hypothyroidism is about 2%–5% per year. The risk increases with a high level of serum TSH level and the presence of thyroid peroxidase-specific antibodies.[13,14]

Initiation of treatment with hormone replacement therapy or levothyroxine for SCH is controversial. Most of the guidelines recommend hormone replacement therapy or

Table 6: Comparative effect of both the interventions on weight and body mass index (unpaired *t*-test)

Variable	*n*	Group	Difference mean	SD±	SE±	*t*	*P*	Results
Weight (kg)	10	A	1.00	1.054	0.333	0.198	>0.05 (0.845)	NS
	11	B	0.91	1.044	0.315			
BMI (kg/m^2)	10	A	0.43	0.506	0.160	0.423	>0.05 (0.677)	NS
	11	B	0.35	0.408	0.123			

n: Total number of patients, NS: Nonsignificant, SD: Standard deviation, SE: Standard error, *P*: Probability value, BMI: Body mass index

Table 7: The effect of therapy on renal and liver function test (paired *t*-test)

Variable	*N*	Group	Mean		Mean difference	Percentage relief	SD±	SE±	*t*	*P*	Results
			BT	AT							
SGOT (U/L)	10	A	31.59	28.57	3.02	9.56↓	14.011	4.431	0.682	>0.05 (0.513)	NS
	11	B	30.94	30.30	0.63	2.03↓	10.526	3.174	0.201	>0.05 (0.845)	NS
SGPT (U/L)	10	A	36.45	31.82	4.63	12.70↓	21.066	6.662	0.695	>0.05 (0.505)	NS
	11	B	30.22	29.46	0.76	2.51↓	11.561	3.486	0.219	>0.05 (0.831)	NS
Blood urea (mg/dl)	10	A	20.42	19.44	0.98	4.80↓	4.834	1.529	0.641	>0.05 (0.537)	NS
	11	B	21.03	21.66	−0.625	2.97↓	5.177	1.561	−0.400	>0.05 (0.697)	NS
Serum creatinine (mg/dl)	10	A	0.850	0.840	0.010	1.18↓	0.0738	0.0233	0.429	>0.05 (0.678)	NS
	11	B	0.873	0.874	−0.0009	−0.10↑	0.134	0.0405	−0.0225	>0.05 (0.983)	NS

↓: Decrease, ↑: Increase, NS: Nonsignificant, SD: Standard deviation, SE: Standard error, BT: Before treatment, AT: After treatment, *P*: Probability value, SGOT: Serum glutamic oxaloacetic transaminase, SGPT: Serum glutamic pyruvic transaminase

levothyroxine in SCH when the serum TSH level is more than 10 mIU/L.[15] There is no evidence of benefits or reduction in harms for treatment of SCH with levothyroxine. Treatment of SCH with levothyroxine has also a concern for lifelong drug dependency and adverse effects of the drug. In addition, patients,[16] particularly female patients of SCH, are more health-conscious about gradual weight gain and menstrual abnormalities and also feel anxious about deterioration or converting to overt hypothyroidism if not treated.

Findings of the present study suggest that *Vyoshadi Guggulu* and *Shadushana Churna* have significantly decreased serum TSH levels by 16.61% and 26.29%, respectively. A decrease in BMI by *Vyoshadi Guggulu* and *Shadushana Churna* was 1.80% and 1.36%, respectively, which was statistically significant. The difference in the decrease in serum TSH and BMI through *Vyoshadi Guggulu* and *Shadushana Churna* was statistically not significant.

The practical utility of the findings of this study is that *Vyoshadi Guggulu* and *Shadushana Churna* may be useful to lower the serum TSH level and reduce or prevent further weight gain in patients of SCH where no treatment is recommended or not any evidence for benefits with treatment in western medical science. The efficacy of these drugs on the menstrual problem related to the condition needs to be explored. No adverse effect of trial drugs was reported throughout the study. It implies that the drugs are safe for use. The findings of this trial are based on the treatment of a fewer number of patients. It needs to be verified through well-designed randomized controlled trial with an appropriate sample size.

Probable mode of actions of trial drugs

Contents of *Vyoshadi Guggulu* such as *Shunthi (Zingiber officinale* Rosc.*)* , *Pippali (Piper longum* Linn.*), Haritaki (Terminalia chebula* Retz.*), Vibhitaka (Terminalia bellirica* Roxb.*), Amalaki (Emblica officinalis* Gaertn*), Kanchanaara (Bauhinia variegate* Linn.*), Guggulu (Commiphora mukul* Engl*)*, and *Madhu* (honey) have predominantly *Katu* (pungent)*, Tikta* (bitter) *Rasa, Laghu, Ruksha, Teekshna Guna, Ushna Veerya and Katu Vipaka*. *Tikta Rasa* has *Lekhana Guna* that scraps out excessive *Kapha* and *Meda* from the *Srotasa* (microchannels). *Katu Rasa* increases *Vata* and *Pitta* while decreases *Kapha* and stimulates the digestive fire. It removes the obstruction and thus corrects the *Srotorodha.* Hence, it is apparent that by their *Rasas*, these drugs are likely to have *Kaphashamaka* and *Medohara* properties. *Teekshna Guna* acts on the channels immediately and removes the obstruction. These *Guna* also activate the *Jatharagni* and *Dhatwagni* and maintain their normal physiological status. *Ushna Veerya* is accountable for increasing the basal metabolic rate and oxygen consumption and accelerates the breakdown of fat at the mitochondrial level. The majority of the drugs have *Katu Vipaka* which enhances the *Jatharagni* and *Dhatwagni* and normalizes the metabolic processes. *Katu Vipaka* drugs reduce the *Kapha* and *Meda* contents of the body.

Kanchanaar is one among the contents of *Vyoshadi Guggulu* and indicated in thyroid gland dysfunctions and releases thyroidal hormones. *Guggulu* or *Commiphora Mukul* possesses thyroid stimulating activity and it reduces cholesterol and stimulates phagocytosis by increasing leukocytes.[17-19]

Shadushana Churna contains *Pippali, Pippalimoola, Chavya, Chitraka, Shuthi,* and *Maricha. Pippali* has been mentioned as *Deepaniya, Paachaniya* and *Anahaprashamana* by *Acharya Charaka*. The contents of *Shadushana Churna* by their *atu Rasa* and *Ushna Veerya* lead to stimulation of *Agni* and mitigate vitiated *Kapha Dosha*. In most Ayurvedic classics, *Pippali* has been stated to be "*Yogvahi Dravya"* which means that when *Pippali* is combined with other drugs, it potentiates their activities by maintaining its pharmacological actions.[20]

Safety of trial drugs

No adverse effect of drugs was observed during the entire clinical trial and liver function tests as well as renal function tests were within normal limits before and after treatment. Hence, it can be said that both the trial drugs are safe for mentioned doses for clinical practice.

Conclusions

Vyoshadi Guggulu and *Shadushana Churna* are clinically safe and effective in the management of SCH. *Vyoshadi Guggulu* and *Shadushana Churna* are statistically equally effective to reduce serum TSH and BMI in patients with SCH. *Shadushana Churna* is clinically better to reduce elevated serum TSH levels than *Vyoshadi Guggulu. Vyoshadi Guggulu* can be a choice of drug for obese cases and *Shadushana Churna* can be a choice of drug for nonobese cases of SCH.

Recommendation for future research work

1. It is recommended that a randomized clinical trial on a larger number of patients should be carried out to confirm and establish the efficacy of *Vyoshadi Guggulu* and *Shadushana Churna* in SCH
2. The future study should be carried out on two strata of patients like obese and nonobese cases of SCH and the efficacy of *Vyoshadi Guggulu* in obese patients and *Shadushana Churna* in nonobese patients of SCH should be explored.

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Conflicts of interest

There are no conflicts of interest.

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