



A CLINICAL STUDY ON THE EFFECTIVENESS OF VIRECHANA IN HYPOTHYROIDISM

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ABSTRACT:

Background: The contemporary stress-filled lifestyle has created a shift in the activities of neuro-endocrine systems, resulting in a surge of newer metabolic health challenges including such hypothyroidism. It is a new health concern that affects millions of people worldwide, impacting productivity and work. Since there is no explicit mention of hypothyroidism in classical treatises, the disease can be viewed as a *tridoshaja vyadhi* (~imbibed with three bio humors) with *agnimandya* (~weakening of digestion) at the *dhatu*(~tissues) and *srotodusti* (~ defects within channels) levels. *Virechana* (~medicated purgation) is a commonly used procedure in panchakarma for *srotoshodhana*(~cleansing the microchannels), *agni*(~digestive fire) correction, and *bahudosh*(~increase in biohumors) removal from the body. As a result, *virechana* will be evaluated and validated clinically in hypothyroidism. **Objective:** To evaluate the effectiveness of *virechana karma* in hypothyroid patients. **Methods:** A convenient sampling method was employed to choose 30 hypothyroid subjects. *Deepana pachana* (~procedures for improving agni) performed *abhyantara rookshana* (~internal drying) with *chitrakadi vati* 500gms twice daily before food and *panchakola phanta* 50ml twice daily before food until the appearance of *samyak rookshana lakshanas* (~proper symptoms of drying). They were given *snehapana* (~intake of oral sneha) with *varunadi ghrita* until *samyak snigdha lakshanas* (~symptoms of proper oleation) emerged, then *vishrama kala* (~resting phase) for three days. *Virechana* with *avippatikara choorna* 25gms, was given as *anupana*(~adjuvant) with honey. After finally completing *Samarjana krama* (~post dietary regimen), subjects were given *Kanchanara guggulu* for 15days. BILLECWICZ SCORE was implemented to analyse subjects 15 days after completing *samsarjana krama*. **Results:** There were a marked improvement in signs and symptoms, along with a reduction in serum TSH levels. **Conclusion:** *Virechana* proved effective in management of hypothyroidism, so this new modality of treatment needs to be validated through a well-planned study on a large sample size.

Keywords: Ayurveda, *Avippatikara choorna*, Hypothyroidism, *Mandagni Srotosodhana*, *Virechana*

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INTRODUCTION:

According to forecasting from various thyroid disease studies, 42 million people in India suffer from thyroid disorders, with hypothyroidism being the most common with a prevalence of 5.4%.¹ Given the high prevalence rate of this disease in today's stressful and strenuous living, its influence on the individual's quality of life, and the tedious process of taking thyroid supplements for the rest of life, an alternative management appears to be the need of the hour.

Hypothyroidism is categorised as any condition that results in a lack of thyroid hormone, including hypothalamic or pituitary disease, generalised tissue resistance to thyroid hormone, and disorders that affect the gland directly.² It encompasses a widespread therapeutic spectrum, spanning from an asymptomatic or subclinical condition with normal thyroxine (T4) and triiodothyronine (T3) levels and mildly elevated serum TSH levels to an overt state of myxoedema and multi-system failure.³ Although there is no direct resemblance to any disease, it is possible to associate the presentation of the disease with some concepts mentioned in the classics, for instance, *asthaninditiya purush*(~inacceptable 8 bodily traits) encompasses many endocrinal presentations, *galaganda*(~goitre) resembles the goitre

manifestation of hypothyroidism, symptomatology in hypothyroidism match with different conditions such as *rasapradoshaja vikara*(~diseases due to improper rasa *dhatu*),*kaphajagrahani*,*kaphaavritvata*.In *rasapradoshaja vikara*, *langhan* is the treatment as well as *virechana* is one of the *shodanarupi langhana*. *Virechana* is an excellent treatment for pitta, samsrushta, *vata*, and *kapha doshas*, in addition to *sannipataja* conditions.⁴

AIMS AND OBJECTIVES:

To study the effectiveness of *virechana karma* in hypothyroidism.

MATERIALS AND METHODS:

Ethical committee approval number: IEC No: **SDM/IEC/39/2020**

CTRI Registration no: **CTRI/2021/03/042126**

Source of data: Patients attending the in-patient department of Sri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital, Hassan.

Method of collection of data:

A. Screening: Subjects fulfilling the diagnostic criteria enumerated beneath will be screened using a screening form, and patient information will be gathered using a specifically designed case report form (CRF).

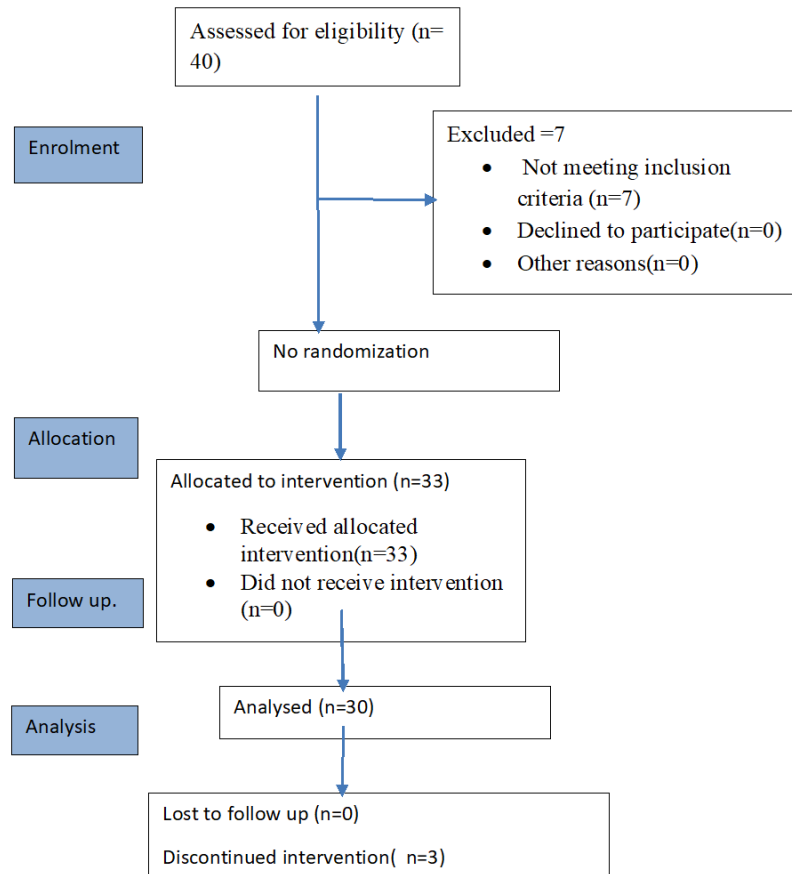


Fig. 1 : Consort Flow Chart

B. Diagnostic criteria: Thyroid stimulating hormone (serum TSH) value more than 4.5mIU25 which may or may not be associated with decreased levels of T3 and T4.

Research design: An open label, single arm, prospective clinical study of hypothyroidism in at least 30 patients from the in-patient department of a tertiary Ayurveda hospital affiliated with an Ayurveda Medical College in the district headquarters of Southern India, Sri Dharmasthala Manjunatheshwara College of Ayurveda and Hospital, Hassan.

Clinical study protocol

Sampling method: A minimum of 30 patients fulfilling the diagnostic and inclusion criteria

will be selected by convenient sampling method and will be considered in a single group.

Intervention

Poorva karma: a) **Abhyantara rookshana**(~internal dehydration therapy)-
*Deepana -pachana with chitrakadi vati*⁵
500mgs twice daily before food
*Panchakola phanta*⁶ 50ml twice daily before food till the appearance of *samyak rookshana lakshanas*.

b) **Bahya rookshana**(~internal dehydration therapy) : *Udwartana*(~powder massage) was done with *triphaladi choorna* followed by *baspa sweda*(~fomentation in steam cabinet)

till the appearance of *samyak rookshana lakshanas*.

Snehapana(~oral intake of fats)

It was done with *varunadi ghrita*⁷ in *arohana krama matra*(~pattern of increasing dosage)till appearance of *samyak snigdha lakshanas*.

Abhyanga and swedana

During *vishrama kala*, *abhyanga* with *moorchita tila taila*⁸ was done followed by *baspa sweda*

Pradhana karma: Sarvanga abhyanga (~body massage with oil) with *moorchita tila taila* followed by *baspa sweda*

Virechana with *avippatikara choorna*⁹ 25gms, with *madhu* as *anupana*.

Paschat karma

Paschat karma: Samsarjana krama was based on the type of *shuddhi*(~purification)

Follow up medicine: *Kanchanara guggulu*¹⁰ 500mgms twice daily before food was given for 15 days after completion of *samsarjana krama*.

Duration of study: *Rookshana Karma* (1st - 3rd) day until *samyak rookshana lakshanas* appear

Snehapana (4th- 10th) day or till *Samyak Snigdha lakshanas* appears.

Vishrama kala after *Samyak Snigdha lakshanas* (11th -13th) day for 3 days

Virechana karma-14th day.

Samsarjana krama-(15th -21st) day based on the *shuddhi* attained.

Diagnostic criteria

Inclusion criteria: 1) Subjects who are diagnosed with hypothyroidism with or without oral thyroxin therapy. 2) Subjects fit for *virechana karma*. 3) Those subjects who are willing to participate in the study and are ready to sign the consent form. 4) Age of the subject should be between (18-60) years. 5) Inclusion of subjects in the study will be done irrespective of gender.

Exclusion criteria: 1) Patients who have undergone any type of thyroid surgery. 2) Patients suffering from congenital hypothyroidism, drug induced hypothyroidism, progressive case of myxoedema, secondary hypothyroidism. 3) Systemic diseases like ischemic heart disease, renal impairment and hepatic impairment. 4) Hypothyroidism in pregnancy and during lactation.

Assessment criteria: Primary outcome

measure: Assessment of objective parameters was based on the changes in laboratory parameter serum TSH on 1st day and 15 days after *samsarjana karma*.

Secondary outcome measure: Assessment of subjective parameters will be done with the help of a suitable clinical scoring of hypothyroidism- 'BILLEWICZ SCORE'¹¹ on 1st day and 15days after *samsarjana karma*.

Statistical analysis: Results were analysed using appropriate statistical test based upon type of data like Friedman's test and post hoc Wilcoxon sign rank test using SPSS version.

Paired T Test is used to analyze the significance of change in TSH values before and after treatment.

Wilcoxon sign rank test was used to assess BILLEWICZ SCORE before and after treatment.

Observation and results

- Based on this study majority of the subjects were from the age group 20 – 30 years with 13(43.3%) subjects. Among patients 7 (23.3%) belonged to the age group 31-40 years. 8 (26.7%) belonged to the age group 41 – 50 years. 2 (6.7%) belonged to the age group (51 - 60) years.
- Based on this study majority of the patients were females compared to males. Among 30 patients 26 (84.7%) were females and 4 (13.3%) was male.
- Based on this study, majority of the patients belonged to Hindu religion. Of 30 patients, 30 (100%) belonged to Hindu religion.
- Based on this study, majority of the patients were married. Of 30 subjects, 19(63.3%) were married and 6(20%) were single and 5(16.7%) were widowed.
- Out of 30 subjects, family history of hypothyroidism was present in 10(33.3) % and absent in 20(66.7%) subjects.
- Based on this study, majority followed mixed diet. Of 30, 26(87.5%) followed mixed diet. 5 (12.5%) followed vegetarian diet.
- Based on this study, majority practiced *madhura rasa pradhana ahara*(~diet consisting of sweet taste). Out of 30, 10 (35.5%) practiced *madhura rasa pradhana ahara*. 5 (16.3%) practiced *katu rasa pradhana ahara*(~pungent taste).15(50.3%) practiced *sarvarasa*(~all six tastes).
- Based on this study, majority of patients consume *samashana*. Out of 30, 6 (25%) indulged in *samashana*. 20 (62.5%) indulged in *vishamashana* and 4(12.5%) in *adhyashana*.
- The above table depicts distribution of type of *kostha* in 30 patients of Hypothyroidism. Based on this study, out of 30 patients, 18 (60%) had *madhyama kostha* and 6(20%) had *kroora kostha* and 6(20%) had *Mridu kostha*.
- Out of 30 patients, Agni was found to be *Manda* in 18(60) %, *Vishama* in 7 (30 %) subjects and *Sama* in 4(13.3) %.and *teekshna* in 1(3.3%).
- Out of 30 subjects, 20 (66.7%) had regular *malapravrutti*(~type of bowel habits) and 10 (33.15%) had irregular *malapravrutti*.
- Out of 30 patients, 15 (50%) subjects had hard stools and 15 (50%) had normal consistency of stools.
- Based on this study, majority had irregular menstrual cycle. Out of 30, 16(36%) patients

had irregular menstrual cycle. 6 (20.6%) patients had regular menstrual cycle. 5 (16.7%) had attained menopause. And in 3 (10%) it was not applicable.

- Based on this study, 11(36.7%) had obese and overweight each and 8(20%) had normal BMI.
- Based on this study, majority did not present with thyroid swelling. 28 (93.3%) patients did not have thyroid swelling and 2 (6.7%) had thyroid swelling
- Based on this study, majority took thyroid supplements. 16 (53.3%) patients took thyroid supplements while 14(46.7%) did not take supplements
- Out of 30 patients 4 patients i.e. 13.3% of patients had taken *Snehapana* ranging from (200-349) ml and 19 i.e. 63.3% of patients had taken *Snehapana* ranging from (350- 499) ml and 7 i.e. 23.3% of patients had taken *Snehapana* ranging from(500-700)ml in the whole course of *Virechana* procedure
- Out of 30 patients, 10 i.e., 33.3% of patient had taken *Snehapana* for 3 days and 13 i.e.,

43.3% of patient had taken *Snehapana* for 4 days and 7 i.e., 23.3% of patient had taken *Snehapana* for 5days.

- Out of 30 patients, 10 (33.3%) patients had *Virechana Vegas* and 14 (72%) patients had (16-23) and 06 (20%) of patient had (24 -30) *Virechana Vegas*.

Out of 30 patients, *Virechana Vegas* had started within the first hour for 4(13.3%) and for 26(86.7%) it occurred after the first hour.

Out of 30 patients, *kaphantaki shuddhi* of *virechana* was for 4(13.3%) subjects and for 26(86.7%) it was not present.

Out of 30 patients, 4 (13.3%) patients had *pravara shuddhi* and 19 (63.3%) patients *madhyama shuddhi* and 7(23.3%) of patient had *avara shuddhi*.

Results were analysed using appropriate statistical test based upon type of data such as McNamar test, paired t test and Wilcoxon sign rank test using the SPSS software version 23 (Statistical Package for Social Science, IBM, Armonk, New York, USA

Table1: Effect of virechana on diminished sweating

BT	AT		N	P value	Remarks
Present	11	19	30	0.01	S
Absent	0	0			

BT-Before treatment, AT-After treatment P Value- level of significance N- Number of subjects S-Significant NS – Non-Significant.

There was a statistically significant difference in diminished sweating with McNamar’s test before and after treatment with p value less than 0.05

Table 2: Effect of virechana on dry skin

BT	AT		N	P value	Remarks
Present	3	23	30	0.01	S
Absent	0	0			

There was a statistically significant difference in dry skin with Mc Nemars test before and after treatment with p value less than 0.05.

Table 3: Effect of virechana on hoarseness of voice

BT	AT		N	P value	Remarks
Present	3	2	30	0.01	S
Absent	0	25			

There was a statistically significant difference in hoarseness of voice with Mc Nemars test before and after treatment with p value less than 0.05.

Table 4: Effect of virechana on increase in weight

BT	AT		N	P value	Remarks
Present	1	26	30	0.01	S
Absent	1	2			

There was a statistically significant difference in increase in weight with Mc Nemars test before and after treatment with p value less than 0.05.

Table 5: Effect of virechana on slow movement

BT	AT		N	P value	Remarks
Present	6	12	30	0.03	S
Absent	1	11			

There was a statistically significant difference in slow movement with Mc Nemars test before and after treatment with p value less than 0.05.

Table 6: Effect of virechana on constipation

BT	AT		N	P value	Remarks
Present	11	19	30	0.01	S
Absent	0	0			

There was a statistically significant difference in constipation with Mc Nemars test before and after treatment with p value less than 0.05.

Table 7: Effect of virechana on periorbital puffiness

BT	AT		N	P value	Remarks
Present	4	11	30	0.05	NS
Absent	1	14			

There was a statistically significant difference in periorbital puffiness with Mc Nemars test

Table 8: Effect of virechana on cold skin

BT	AT		N	P value	Remarks
Present	5	23	30	0.05	NS
Absent	2	0			

There was no statistically significant difference in cold skin with Mc Nemars test before and after treatment where p value less is 0.05.

Table 9: Effect of virechana on coarse skin

BT	AT		N	P value	Remarks
Present	5	18	30	0.01	S
Absent	1	16			

There was a statistically significant difference in coarse skin with Mc Nemars test before and after treatment with p value less than 0.05.

Table 10: Effect of virechana on delayed ankle reflex

BT	AT		N	P value	Remarks
Present	4	11	30	0.01	S
Absent	0	15			

There was a statistically significant difference in delayed ankle reflex with McNemars test before and after treatment with p value less than 0.05.

Table 11: Table showing effect of virechana on TSH

Parameter	Mean		Mean Diff	SD	SE	T	P	Remarks
	BT	AT						
Serum TSH	14.20	7.46	6.732	6.659	1.216	5.537	0.001	S

Serum TSH: In 30 patients of hypothyroidism, serum TSH was 14.20 micro IU/ml before treatment and it decreased to

7.46 micro IU/ml after treatment with decrease of 6.732 micro IU/ml. The decrease in the value is statistically significant.

Table 12: Table showing effect of virechana on Gross BILLEWICZ SCORE

Parameter		N	Mean rank	Sum of Ranks	Z value	P value	Remarks
BILLEWICZ SCORE before and after treatment	Negative ranks	30	15.00	465	-4.783	.001	S
	Positive ranks	0	0.00	0.00			
	Ties	0					
	Total	30					

BILLEWICZ SCORE before and after treatment was assessed by Wilcoxon signed rank test before and after treatment. There was no patient where the TSH values increased after treatment and there were no patients where

values did not change before and after treatment. All patient showed improvement in TSH after treatment. As 'p value' was less than 0.05 ,so there was significance before and after treatment.

DISCUSSION

Even if it is an *anukta vyadhi*, clinical manifestations can be used to perceive the pathogenic mechanisms of hypothyroidism.

Thyroid hormones stimulate various metabolic activities in tissues, elevating the basal metabolic rate, and hence behave identically to agni. *Agnidushti* occurs as a result of various poor dietary habits and lifestyle modification, resulting in the formation of ama and symptoms such as *bala bhramsa* (~tiredness), *mala sanga* (~constipation), and *gaurava* (~fatigue). Mandagni to a specific *dhatu* induces the manifestation of *srotodushti lakshanas*, which can be interpreted as hypothyroidism signs and symptoms. Along with *rasa dhatu*, *uttarotara dhatu* (~subsequent tissues) become vitiated and produce symptomatology. *Agnimandya* emerges as *lakshanas* such as *aruchi* (~loss of appetite), *gaurava* (~heaviness of the body), *tandra* (~lassitude), *angamarda* (~bodyache), *panduta* (~pallor), *klaibya* (~loss of libido), and *Saada* (~lethargy) at the *rasa dhatu* level. This is clarified by the signs and symptoms of hypothyroidism, that include diminished appetite, fatigue, anaemia, puffy eyes of the eyes, decreased libido, and puffiness of the face. At the *rakta dhatu* level, *lakshanas* such as *twak vikara* (~skin disorders), *svitra* (~vitiligo), and *vyanga* (~melasma)

manifest as dry, coarse skin and facial hyperpigmentation in hypothyroid patients. The depictions of *lakshanas* at *mamsa dhatu* are *galaganda* (~swelling in neck region) and *gandamala* (~goitre), which can be inferred as manifestations of multiple kinds of goitre. Mandagni at *medo dhatu* causes the expression of *lakshanas* such as *sthoulya* (~obesity) and *swasa* (~breathing difficulty) during *alpa cheshta*, which can be clarified by hypothyroidism symptoms including weight gain and dyspnea. In hypothyroid patients, *Mandagni* at *Asthi Dhatu* causes the manifestation of *lakshanas* like *kesha dosha* (~hair disorders), *nakha dosha* (~nail disorders), and *asthi bheda* (~brittle bones), in addition to hair loss and brittle nails. *Mandagni* at *majja dhatu* provokes the manifestation of *lakshana*, particularly *parva ruk* (~pain in the thigh area) which again is arthralgia, muscle stiffness, and hypothyroidism. *Mandagni* at *shukra dhatu* generates the occurrence of *lakshana*, primarily *klaibya* (~infertility), *aharshana* (~loss of vigor), *garbha pata* (~abortions of fetus at late months of conception), and *garbha sraava* (~abortions at the early phase of conception) , which again is loss of libido, menstrual abnormality, erectile dysfunction, and infertility.

Probable mode of action of virechana: And since *bahu dosha* was associated in the hypothyroidism, *doshavsechan* in the manner of *virechana* was planned. It was planned this way because hypothyroidism is primarily a metabolic disorder with interrupted metabolism at the cellular level. *Virechana* act at the microcellular level and help to maintain normal tissue physiology by removing metabolic toxins. Waste products present in the body, regardless of whether extracellular, intracellular, or plasma, are brought into the intestine and eliminated from the system. *Virechana* enhanced thyroid hormone production and proper release by activating metabolic enzymes such like peroxidase A. As a result of the negative feedback system via the Hypothalamo-Pituitary-Thyroid axis, TSH levels were lowered.

Mode of action of trial drugs: The drug *varunadi ghrita*, with which *snehapana* was conducted consists of drugs with *tikta rasa pradhana*, *laghu*, *ruksha guna*, and *ushna veerya* and were *kapha medohara*, *mandagni nashaka*, and *tridoshahara*.

Avippatikkara churna has *katu, tikta, laghu, ruksha, ushna, sheeta veerya, madhur,* and *katu vipaka* and *trivrit*(~*Operculina turpethum*) is the main component, accounting for 44 percent of the total formulation. There is *agnimandya* due to

kaphasanchaya in hypothyroidism, and *vata pratilomata* due to *avarana* as a consequence of *sanchita kapha*. *Trivrit* accomplishes *ruksha virechana*, which facilitates in the removal of *kapha sanchaya* and the induction of *vata anulomana deepana, pachana, lekhana, strotoshodhan, anulomana,* and *kaphashamaka*. Drugs in *Kanchanara guggulu* are likely to inhibit the basic pathogenesis of hypothyroidism, i.e., hypometabolism.

CONCLUSION

This research concluded no adverse effects. In subsequent follow-ups, the subjects' thyroxin supplement dosage was reduced. The trial drugs resulted in significant improvements on both primary and secondary outcome measures. The clinical trial analysis shows that *virechana* is effective for the treatment of hypothyroidism.

Limitations of the study: 1. The procedure was found more effective in subjects with TSH values less than 15mIU/L.

2. *Varunadi ghrita* had issues with palatability.

3. Shaman *aushadhi* like *Kanchanara guggulu* given after *samsarjana krama* for 15 days had an add on therapy in the subjects, so only saying only *virechana* is effective would not be a valid claim.

4. Dosage of *virechana* was fixed for standardisation with *avippatikara choorna*

25grams for madhyama kostha subjects which proved less effective in kroora kostha subjects.

Scope of further study: The study was undertaken in a small sample, so for further study with large sample should be done to establish the study more effectively.

Financial support and sponsorship: Nil.

Conflicts of interest: There are no conflicts of interest.

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