



Research Article

www.ijrap.net

(ISSN Online:2229-3566, ISSN Print:2277-4343)



A SINGLE-ARM CLINICAL STUDY TO EVALUATE THE COMBINED EFFECTIVENESS OF UDVARTANA AND ERANDAMOOLADI KALA BASTI IN THE MANAGEMENT OF HYPOTHYROIDISM

Rosy Nandi ¹, Ashvini Kumar M ², Kavita MB ^{3*}, Krishna Teja ⁴, Pooja PK ⁴

¹ PhD Scholar, Department of Panchakarma, SDM College of Ayurveda and Hospital, Hassan, Karnataka, India

² Professor, Department of Panchakarma, SDM College of Ayurveda and Hospital, Hassan, Karnataka, India

³ Professor, Department of Swasthavritta SDM College of Ayurveda and Hospital, Hassan, Karnataka, India

⁴ PG Scholar, Department of Panchakarma, SDM College of Ayurveda and Hospital, Hassan, Karnataka, India

Received on: 08/8/24 Accepted on: 28/9/24

*Corresponding author

E-mail: drmbkavita@sdmcahassan.org

DOI: 10.7897/2277-4343.155158

ABSTRACT

The lifestyle of the modern era has led to alternation in the activities of the neuro-endocrine system causing newer health challenges such as hypothyroidism. TSH value >4.5 mIU/L, is diagnosed as hypothyroidism with features of slow metabolic rate, weight gain, and dry and cool skin. The prevalence of hypothyroidism in India is 11%. Women are affected approximately 6 times more frequently than men. In Ayurveda, the clinical presentation of hypothyroidism can be understood in terms of santarpanotha vikara with tridosha dushti. The pathogenesis revolves around Ama which is formed by agnimandya with predominance of rasa and medodushti. Rukshana upakrama is the first opinion of therapy for such a condition. The study aims to evaluate the combined effectiveness of Udvartana and Erandamooladi Kala Basti in managing hypothyroidism. A total of 20 subjects diagnosed with hypothyroidism, aged between 20-60 years were given Udvartana and Erandamooladi Kala Basti for nine days. The assessment was based on body fat percentage, visceral fat percentage, serum TSH values, and Zulewski's clinical score. Statistical analysis showed a significant reduction in Visceral fat percentage, TSH value, and Zulewski's clinical score with p-value <0.05. Udvartana karma pacifies Kaphavata dosha, liquefies the medas, and softens the skin. Erandamooladi Basti kindles digestive fire, has scarifying properties, and is indicated in Kaphavata avarana. The combined effectiveness of Sarvanga Udvartana and Erandamooladi Basti had a considerable impact on managing hypothyroidism.

Keywords: Erandamooladi Basti, Hypothyroidism, Udvartana, Zulewski's clinical score, Body fat percentage, Visceral fat percentage.

INTRODUCTION

The lifestyle of the modern era has led to alternation in the activities of the neuro-endocrine system causing newer health challenges such as hypothyroidism. Since Hypothyroidism is a risk factor for developing Diabetes, Dyslipidaemia, and Hypertension, if left untreated, it may lead to end organ failure. Serum TSH (Thyroid Stimulating Hormone) value >4.5 mIU/L, is diagnosed as hypothyroidism with features of slow metabolic rate, weight gain, dry, cool skin etc. The prevalence of hypothyroidism in India is 11%. Women are affected approximately 6 times more frequently than men.¹ Common causes are autoimmune diseases such as Hashimoto's thyroiditis and Atropic thyroiditis, surgical removal of the thyroid gland, radiation treatment, medicines such as amiodarone, lithium, inferno alpha, and interleukin-2, too much or too little iodine, damage to the pituitary gland, disorders that infiltrate the thyroid such as Amyloidosis, Sarcoidosis, Hemochromatosis². Hypothyroidism cannot be cured but can be managed by synthetic thyroxine pills with a daily dose of 1.6 µg/kg body weight. This hormonal replacement therapy makes the patient drug-dependent lifelong and has a host of side effects from excessive doses including weight loss, trouble tolerating heat, sweating, anxiety, trouble sleeping, tremor, and fast heart rate³. Hence a measure to arrest further progress of disease is the need of time. In Ayurveda, the clinical presentation of Hypothyroidism can be understood in terms of santarpanotha vikara (group of diseases which arises due to sedentary lifestyle) with tridosha dushti. There is an increase

in guru, manda guna, and agnimandhya (weak digestive fire) due to irregular food habits and lifestyle. Hypothyroidism is one of the endocrine and metabolic disorders that involve agni dushti and the pathogenesis revolves around Ama (undigested food that gets absorbed into the system without proper assimilation). Agni may be understood as metabolic-related chemicals and enzymes in the body. The line of management includes deepana, pachana, srotoshodhana, and Kaphavata pacification. Rukshana upakrama (dryness therapy) is the prime treatment modality adopted in such a condition. One which produces dryness, roughness, and non-sliminess in the body is known as Rukshana⁴. Rukshana is indicated conditions arising from diseases due to obstruction of channels, highly aggravated condition of doshas, diseases which affect vital points, stiffness of thigh, and other such conditions⁵ Udvartana and Niruha Basti both have Rukshana karma. With this rationale, Udvartana and Erandamooladi Basti were selected for the present study. Udvartana is a technique in which medicated powder is massaged in the direction opposite to the hair root of the body. It pacifies kapha dosha and causes liquefaction of medas, it gives stability to the body parts and, improves skin texture⁶. Drugs administered rectally will have a faster onset, higher bioavailability, shorter peak, and shorter duration than the oral route. Hence Basti has been chosen for the present study. The approach of this study was to provide an effective, comprehensive, and rational option for the management of Hypothyroidism. The present study aims to evaluate the combined effectiveness of Udvartana and Erandamooladi Kala Basti in the management of hypothyroidism.

MATERIALS AND METHODS

It was an open-label, single-arm, clinical study where subjects diagnosed with hypothyroidism were selected by the convenient sampling method. The present study was undertaken at Tertiary Ayurveda Hospital, Hassan, Karnataka from January 2022 to December 2022. Ethical clearance was obtained from the Institutional Ethics Committee (SDM/IEC/109/2020) before the commencement of the study. Subjects attending the outpatient and inpatient departments during this period were screened for hypothyroidism. Those with TSH values ranging from 5-30 mIU/L, aged between 20 - 60 years of all genders, specifically fit for Udvartana and Basti karma were included in the study after getting the consent form signed. Hypothyroid cases suffering from endocrine disorders other than primary hypothyroidism, and established cases of cardiac, metabolic, or systemic disorders were not included in the study. Also,

hypothyroidism in pregnant and lactating women, known cases of myxedema, toxic goiter, post-iodine or post-operative case of hypothyroidism, and any conditions which may jeopardize the study were excluded.

Assessment criteria: The overall effects of the therapy were assessed for body fat percentage and visceral fat percentage (using Omron body fat monitor HBF-375), Serum TSH value and Zulewski's clinical score for hypothyroidism⁷.

Twenty subjects satisfying the inclusion criteria were enrolled in the study. Baseline data was collected in case record form initially at the beginning of the study. Nine days of Sarvanga Udvartana and Kala Basti karma as mentioned in Table 1 was adopted. After completion of the course, the cases were reviewed on the 45th day for final assessment.

Table 1: Intervention schedule

| Intervention | Drug |
|---------------------------------------|--------------------------|
| Sarvanga Udvartana | Triphaladi churna |
| Anuvasana basti (after lunch) | Brihat Saindhavadi taila |
| Niruha basti (morning, empty stomach) | Erandamuladi Basti yoga |

Table 2: Kala Basti schedule

| Day | D1 | D2 | D3 | D4 | D5 | D6 | D7 | D8 | D9 |
|---------|----|----|----|----|----|----|----|----|----|
| Morning | | N | N | N | N | N | N | | |
| Evening | A | A | A | A | A | A | A | A | A |

A-Anuvasana Basti – 80 ml, N- Niruha Basti – 755 ml

Statistical analysis: All the observations were analyzed statistically in terms of mean and standard deviation. Paired t-test was carried out at $p < 0.05$ (improved) and $p < 0.01$ (significant).

Drug Review

Table 3: Ingredients of Triphaladi churna⁸

| Name | Botanical name | Family | Part used |
|-----------|---------------------------------------|---------------|-------------|
| Kulattha | <i>Dolichos biflorus</i> Linn. | Leguminosae | Seed |
| Haritaki | <i>Terminalia chebula</i> Retz | Combretaceae | Dried fruit |
| Vibhitaki | <i>Terminalia belerica</i> Roxb | Combretaceae | Dried fruit |
| Amalaki | <i>Emblica officinalis</i> Gaertn | Euphorbiaceae | Dried fruit |
| Yava | <i>Hordeum vulgare</i> Linn. | Poaceae | Seed |
| Mudga | <i>Phaseolus radiates</i> Linn | Fabaceae | Seed |
| Methika | <i>Trigonella foenum-graecum</i> Linn | Fabaceae | Seed |
| Sarshapa | <i>Brassica campestris</i> Linn | Brassicaceae | Seed |

The dry drugs were purchased and authenticated from the department of Dravyaguna of the Institute. The ingredients were powdered separately, mixed, and sieved with a sieve size no.18 for udvartana purpose. Kwatha churna and kalka churna of Erandamooladi basti yoga⁹ were packed in the pharmacy unit of the institution.

Table 4: Ingredients of Erandamuladi Niruha Basti (Madhyama matra)

| | | |
|--|--------|--|
| Makshika | 190 ml | Kalka* - Shatahva, Hapusha, Priyangu, Pippali, Madhuka, Bala, Rasanjana, Indrayava, Musta Kashaya** - Erandamoola, Palasha, Hrisva Panchamoola, Rasna, Ashwagandha, Atibala, Guduchi, Punarnava, Aragwadha, Devadaru, Madanaphala |
| Saindhava | 10 gm | |
| Brihat saindhavadi taila ¹⁰ | 100 ml | |
| Kalka* | 65 gm | |
| Kashaya** | 290 ml | |
| Gomutra Arka | 100 ml | |

Methodology

Udvartana- For the clinical trial, the amount of powder used was dependent on individual body size. The subject in minimum clothing was made to lie over the massage table. A handful of warm churna was spread all over the body and rubbed one after the other exerting firm pressure in the direction opposite to the root hair of the body. The procedure was performed for 20

minutes in four positions - supine, right lateral, prone, and left lateral.

Basti- Before the administration of Niruha Basti, the lower abdomen and back region were massaged in a circular direction with murchita taila followed by nadi sweda (applying medicated steam through a tube). The classical method of administration of Basti was adopted for Niruha Basti and Anuvasana Basti.

RESULTS AND DISCUSSION

The effect of intervention for body fat percentage and visceral fat percentage were assessed before treatment (BT) and after

treatment (AT) on 9th day. Serum TSH value and Zulewski's clinical score for hypothyroidism were assessed BT and follow-up (FU) on the 45th day.

Table 5: Paired t test for Body fat percentage, Visceral fat percentage and TSH value

| Parameter For n = 20 | Mean | SD | Paired difference | | t | df | Significance (2 tailed) |
|-------------------------|-------|------|-------------------|------|------|----|----------------------------|
| | | | Mean | SD | | | |
| Body fat% BT* | 38.39 | 3.10 | 0.64 | 1.49 | 1.90 | 19 | 0.073 |
| Body fat% AT** | 38.75 | 3.25 | | | | | |
| Visceral fat% BT | 15.83 | 6.87 | 0.40 | 0.70 | 2.56 | 19 | 0.019 |
| Visceral fat% AT | 15.43 | 6.77 | | | | | |
| TSH value BT | 9.25 | 3.70 | 3.02 | 4.10 | 1.68 | 19 | 0.004 |
| TSH value FU*** | 6.23 | 4.14 | | | | | |

*Before treatment (BT) **After treatment (AT) ***Follow-up (FU)

Table 6: Results of Zulewski clinical score for Hypothyroidism

| Ranks | | | | | Wilcoxon Signed Rank Test | Zulewski FU-BT |
|-------------|----------------|-----------------|-----------|--------------|------------------------------------|----------------|
| | | N | Mean Rank | Sum of Ranks | | |
| Zulewski FU | Negative Ranks | 20 ^a | 10.50 | 210.00 | Z | -3.94* |
| Zulewski BT | Positive Ranks | 0 ^b | 0.00 | 0.00 | Asymptotic Significance (2 tailed) | 0.000082 |
| | Ties | 0 ^c | | | *Based on positive ranks | |
| | Total | 20 | | | | |

a.Zulewski FU<Zulewski BT, b. Zulewski FU>Zulewski BT, c.Zulewski FU = Zulewski BT
Before treatment (BT), Follow-up (FU)

Body fat percentage: The mean value of body fat percentage before the trial was 38.39±3.10 and 38.75±3.25 after the trial respectively. Paired T-test before treatment and after treatment with a mean value of 0.64±1.49 is statistically not significant (2-tailed) with a p-value of 0.073.

Visceral fat percentage: The mean value of visceral fat percentage before the trial was 15.83± 6.87 and 15.43±6.77 after the trial respectively. A paired T-test before treatment and after treatment with a mean value of 0.40±0.70 is significant (2-tailed) with a p-value of 0.019 which is statistically significant.

Serum TSH value: The mean value of TSH before trial was 9.25±3.70. After the trial, it was 6.23±4.14 respectively. A paired T-test before treatment and follow-up with a mean value of 3.02±4.10 is significant (2-tailed) with a p-value of 0.004. This suggests that the intervention applied during the trial had a meaningful effect on lowering TSH levels.

Zulewski's clinical score for Hypothyroidism - Wilcoxon Signed Rank Test for Zulewski score after follow-up and before treatment based on positive ranks was significant (2-tailed) with a p-value of <0.0005. This score is an economical and effective tool for identifying clinical hypothyroidism. The subject was clinically considered hypothyroid if the score was ≥5, euthyroid if the score was <3, and intermediate if the score was between 3 and 5. Changes in Zulewski's clinical score for hypothyroidism were significant showing a reduction of dry, cold, and coarse skin, paresthesia, constipation, slowness of movements, weight gain, puffiness of periorbital region, and cold intolerance.

The combined therapy of Udvartana and Erandamooladi Kala Basti has shown promising effect in the management of Hypothyroidism. Erandamooladi Basti is a tikshna basti with most of the drugs having tikshna, ruksha, ushna properties which are antagonistic to ama, kindle digestive fire, pacify Kaphavata, and also checks the medas. It has deepaniya (enhances of power of digestion) and lekhaniya (scarifying) properties and is indicated in conditions of occlusion of vayu by kapha. Brihat Saindhavadi taila has eranda taila as a base with 21 other ingredients. It is mainly used in conditions of Mandagni,

Amavata, and Vata rogas. Most of the ingredients have deepana, pachana, and amahara properties which are beneficial in treating Hypothyroidism. Brihat saindhavadi taila as a part of Niruha Basti and Anuvasana Basti helps in correcting the vitiated Agni. Here taila was preferred because the focus is to control Vata dosha. The procedure showed a significant reduction in the excess of medas since both are rukshana upakrama. At the end of the clinical study, the results showed considerable improvement in body fat percentage and visceral fat percentage exhibiting the lekhana action of the combined therapy. Because of the heat generated by the friction in udvartana, the subcutaneous fat and visceral fat get loosened up. It also stimulates the metabolism; the same can be used up for energy purposes. Hence it helps to manage weight and also tones up the body.

CONCLUSION

Hypothyroidism is a santarpanotha vikara with the involvement of tridosha and agni. Udvartana karma pacifies kapha dosha and causes liquefaction of medas, gives stability to the body parts, and improves skin texture. Erandamooladi Niruha Basti has deepana, lekhana, Kaphavata shamana properties. It can be concluded that the combined therapy of Udvartana and Erandamooladi Kala Basti effectively managed hypothyroidism by reducing visceral fat percentage, TSH and Zulewski clinical score of Hypothyroidism.

Acknowledgment: The authors are grateful to the Institution and acknowledge the cooperation of all the subjects who participated in this study.

REFERENCES

- Davidson SP, Colledge NR, Walker BR, Ralston SH, editors. Davidson's principles and practice of medicine. 21st ed. New York: Churchill Livingstone; 2010. p. 639.
- Thyroid.org.Hypothyroidism [Internet]. Available from: www.thyroid.org/Hypo_brochure Accessed on 20.08.2022
- Levothyroxine Sodium. The American Society of Health-System Pharmacists. Archived from the original on 2016 Dec 21 [cited 2016 Dec 8].

4. Acharya Jadavji Trikamji, Agnivesa, Caraka Samhita with Ayurveda Dipika commentary of Chakrapanidatta, Reprint edition Sutra sthana, Langhana Brihmaniya Adhyaya, Chapter 22, 10th verse Varanasi: Chaukhamba Prakashan; 2013, p. 120
5. Acharya Jadavji Trikamji, Agnivesa, Caraka Samhita with Ayurveda Dipika commentary of Chakrapanidatta, Reprint edition Sutra sthana, Langhana Brihmaniya Adhyaya, Chapter 22, 30th verse Varanasi: Chaukhamba Prakashan; 2013, p. 121
6. Murthy KR Srikantha, English translation on Ashtanga Hridaya of Vagbhata Reprint edition Sutrasthana Dinacharya Chapter 2, 15th verse Varanasi: Chaukhamba Krishnadas Academy; 1999 p. 25
7. Zulewski H, Müller B, Exer P, Miserez AR, Staub JJ. Estimation of tissue hypothyroidism by a new clinical score. J Clin Endocrinol Metab. 1997; 82(3):771-6.
8. Vasant C Patil, Principles and Practice of Panchakarma. 3rd ed. New Delhi: Chaukhamba Publications; 2014; p.143
9. Acharya Jadavji Trikamji, Agnivesa, Caraka Samitha with Ayurveda Dipika commentary of Chakrapanidatta, Reprint edition Siddhi sthana, Bastisutriya siddhi: 3rd Chapter, 38-42nd verse, Varanasi: Chaukhamba Prakashan; 2013, p. 696
10. Kaviraj Sri Ambikadatta Shastri, Bhaishajya Ratnavali with Vaidyatini Hindi Commentary Amavata Chikista Prakarana 29th Chapter, 222-227th verse Varanasi: Chaukhamba Krishnadas Academy; 2001 p. 447

Cite this article as:

Rosy Nandi, Ashvini Kumar M, Kavita MB, Krishna Teja and Pooja PK. A single-arm clinical study to evaluate the combined effectiveness of Udvardana and Erandamooladi Kala Basti in the management of Hypothyroidism. Int. J. Res. Ayurveda Pharm. 2024;15(5):72-75

DOI: <http://dx.doi.org/10.7897/2277-4343.155158>

Source of support: Nil, Conflict of interest: None Declared

Disclaimer: IJRAP is solely owned by Moksha Publishing House - A non-profit publishing house, dedicated to publishing quality research, while every effort has been taken to verify the accuracy of the content published in our Journal. IJRAP cannot accept any responsibility or liability for the site content and articles published. The views expressed in articles by our contributing authors are not necessarily those of the IJRAP editor or editorial board members.