



Research Article

A COMPARATIVE CLINICAL STUDY ON VAMANA KARMA USING MADANAPHALA PIPPALI PROCESSED WITH DIFFERENT BHAVANA DRAVYAS WITH ITS PHYTOCHEMICAL ANALYSIS IN HYPOTHYROIDISM

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ABSTRACT

Vamana karma, is one among the *Panchakarma*, which eliminates the vitiated *Doshas* through the *Mukhamarga*. Hypothyroidism, a prevalent endocrine disorder, occurs due to reduced thyroid hormone production, manifesting as fatigue, cold sensitivity, constipation and weight gain etc. From an Ayurvedic perspective, it can be correlated with *Kaphaja Galaganda*, resulting from an imbalance in *Kapha* and *Vata doshas*. *Vamana karma* is considered as prime therapy for *Kaphaja* disorders. *Madanaphala* being the best drug for *Vamana karma* due to its efficacy and safety. Therapeutic efficacy of a drug depends not only on dose and adjuvants but also on proper collection, processing and storage. *Bhavana samskara* is an important pharmaceutical process that enhances the drug potency by imparting the qualities of the *Bhavana dravya*. Classical texts recommend *Dadhi*, *Madhu* and *Palala* as *Bhavana dravyas* for *Madanaphala*, highlighting their role in improving drug action. Present study seeks to evaluate the therapeutic effect of *Vamana karma* using *Madanaphala Pippali* processed with different *Bhavana dravyas*. **Methodology-** 40 subjects diagnosed with hypothyroidism, meeting the inclusion criteria were randomly assigned into 4 groups, each consisting of 10 subjects. For each group different *Bhavana Madanaphala pippali yoga* was given for *Vamana karma*. Subjective parameters included fatigue, dry skin, loss of appetite, constipation while objective parameters included TSH value and BMI. **Conclusion-** Within the groups, all parameters exhibited significant results. However, comparative assessment of overall treatment outcome revealed statistically no significant difference between the groups. Indicating that each group was equally effective and none showed a definite superiority.

INTRODUCTION

Samshodhana is the purificatory measure aimed at eliminating morbid *Doshas* from the body, thereby addressing the root cause of the disease and preventing its recurrence [1]. *Vamana karma* is one of the most effective purificatory therapies and the prime treatment modality mentioned for *Kaphaja* disorders [2] wherein the vitiated *Doshas* are expelled out through the *Mukhamarga* [3].

In classics numerous formulations are described for the *Vamana karma*, among which *Madanaphala* is regarded as best, most efficacious and distinguished by its *Anapayitva guna*, [4] ensuring consistent therapeutic efficacy without much complications.

An ideal medicine is the one which is given in *Alpamatra*, induces *Mahavega*, *Bahudoshahara*, *Sukhashodhaka*, *Laghupaka*, *Sukhaswada* and *Vyadhinashaka* effects [5]. Apart from *Matra* and *Aanupana*, the efficacy of drug also influenced by proper collection of the drug during appropriate season, processing and storage. Classical pharmaceutics emphasizes that, with an appropriate *Samskara* even a small quantity of a drug can yield enhanced therapeutic outcomes. *Bhavana samskara* is

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one such pharmaceutical process described for *Madanaphala*, which enhances its potency by imbibing the properties of *Bhavana dravya*. According to *Acharya Charaka* and *Vagbhata*; *Ghritha*, *Dadhi*, *Madhu* and *Palala* are recommended as *Bhavana dravyas*^[6,7], whereas *Acharya Sushruta* specifies only *Dadhi*, *Madhu* and *Palala*^[8]. Ensuring the quality of *Madanaphala* through proper collection and enhancing its potency via classical processing method is crucial for maintaining its therapeutic value. In the context of modern pharmacological validation, the assurance of quality and potency in herbal drug is indispensable for substantiating their clinical efficacy.

Vamana karma is indicated in many of the *Kaphaja vyadhis*, one among them is *Galaganda* ^[9,10]. In *Galaganda*, *Kapha* and *Vata* along with *Meda* localize in the *Gala pradesha* leading to swelling^[11]. *Kaphaja Galaganda* can be considered analogous to hypothyroidism. It is one of the common endocrine disorders resulting from inadequate thyroid hormone production. Iodine deficiency remains the leading cause globally; autoimmune disorders and iatrogenic factors predominate in iodine-sufficient regions. Clinically, hypothyroidism is classified as primary and secondary, with primary hypothyroidism accounting for approximately 99% of cases and arising from intrinsic thyroid gland dysfunction, commonly due to autoimmune destruction. Secondary hypothyroidism results from hypothalamic or pituitary pathology. The mean annual incidence rate of autoimmune hypothyroidism is up to 4 per 1000 women and 1 per 1000 men. Subclinical hypothyroidism is found in 6-8% of women and 3% of men. The annual risk of developing clinical hypothyroidism is ~4%^[12]. Common clinical manifestations include fatigue, cold intolerance, dry skin, hair loss, constipation, weight gain despite reduced appetite and menstrual irregularities^[13]. If untreated, the condition may progress to other complications such as obesity, cardiovascular disease, infertility and degenerative joint disorders etc.

The conventional treatment of hypothyroidism is Thyroid Hormone Replacement Therapy i.e. levothyroxine. But levothyroxine has certain side-effects on long term use, it causes cardiac arrhythmia, palpitation, tachycardia, muscle cramps, weakness, restlessness, osteoporosis etc. So, there is a great need to find out a safe and effective remedy which not only relieves symptoms but also increase in sense of well-being leading to more acceptability and better compliance.

A critical conceptual analysis of hypothyroidism in Ayurveda aligns the condition with *Kaphaja Galaganda*, characterized by *Agnimandya* and *Kaphaprakopa*, indicative of a *Bahudosha avastha*. In

such cases, *Shodhana* through *Vamana Karma* is considered the most appropriate therapeutic approach for eliminating vitiated *Kapha dosha*. Although numerous studies have been conducted on *Vamana Karma* with *Madanaphala*, no research has specifically evaluated the efficacy of individual *Bhavana dravyas* with its saponin percentage evaluation. As the potency of a drug may enhance by the appropriate *Bhavana*, the present study was designed to assess both the individual and combined effects of *Bhavana dravyas* on *Madanaphala pippali*, along with its phytochemical analysis. Hence, the present study is undertaken to evaluate the therapeutic effect of *Vamana karma* using *Madanaphala pippali* processed with different *Bhavana dravyas*, supported by phytochemical analysis, with the aim of generating scientific evidence for its clinical utility.

OBJECTIVE

- To compare and analyze the effect of *Vamana karma* with *Madanaphala pippali* processed with *Dadhi*, *Madhu* and *Palala* as *Bhavana dravyas*.
- To evaluate the efficacy of *Bhavita Madanaphala pippali* as *Vamaka yoga* in hypothyroidism.
- To analyse the phytochemical changes of *Bhavita Madanaphala pippali*.

METHODOLOGY

This study was a "Randomized comparative clinical study." In this study, 40 subjects diagnosed with Hypothyroidism and meeting the inclusion criteria were selected. These individuals were randomly assigned into four groups, each consisting of 10 subjects.

Vamana was administered by following proper *Purva*, *Pradhana* and *Pashchat karma*.

Group A - With *Dadhi bhavita Madanaphala pippali*.

Group B - With *Madhu bhavita Madanaphala pippali*.

Group C - With *Palala bhavita Madanaphala pippali*.

Group D - With *Dadhi, Madhu and Palala bhavita Madanaphala pippali*

All subjective and objective parameters were evaluated on the 0th, 16th and 45th day. The condition was assessed using a detailed proforma, employing standardized methods for scoring both subjective and objective parameters. This assessment was subjected to statistical analysis using the paired t test and ANNOVA test. Relevant subjective parameters such as fatigue, dry skin, loss of appetite, constipation and objective parameters as TSH value, BMI were included in the analysis.

Diagnostic Criteria of Hypothyroidism

- Signs and symptoms of hypothyroidism i.e., weight gain, fatigue, dry skin, loss of appetite, constipation.

Elevated TSH levels.

Inclusion Criteria

- Subjects diagnosed with hypothyroidism.
- Subjects fit for *Vamana karma*.
- Subjects aged between 20-60 years irrespective of gender.

Exclusion Criteria

- Subjects associated with uncontrolled diabetes mellitus, hypertension, cardiac ailments, congenital anomalies, carcinoma of the thyroid gland.
- Pregnant and lactating women.

Intervention

Subjects suffering with Hypothyroidism who fulfil the inclusion criteria, were selected and randomly divided into 4 groups, each group consisting of 10 subjects.

Purva karma

Collection and processing of *Madanaphala*

Phytochemical Consultancy Work

Determination of Saponin Content in Different *Bhavita Madanaphala Pippali* Samples

Table 1: Saponin percentage of drug samples

S. no	Samples	% Saponin Content
1.	Simple powder sample	7%W/W
2.	Powder sample + curd	6.8% W/W
3.	Powder sample + honey	4.8% W/W
4.	Powder sample + black sesame paste	3.6% W/W
5.	Powder sample + all mix	3.4% W/W

Preparation of Patient

- Procedure was explained to the subjects and informed written consent was obtained prior participation.
- *Deepana Pachana* was done with *Chitrakadi Vati* 1 TID, before food till the appearance of *Nirama avastha*.
- *Snehapana* with *Moorchita tila taila* till *Samyak snigdha lakshana*.
- *Vishrama Kala- Abhyanga* with *Moorchita tila taila* followed by *Ushnajala snana* for one day. *Kapha utkleshaka ahara sevana* - i.e. curd rice, milk rice, idli and sweet preparation of milk in enough quantity.

Preparation of Medicine

Bhavana of Madanaphala pippali

Madanaphala Pippali was hard and solid; hence, grounded it thoroughly to prepare a fine powder before *Bhavana*. Then 8 to 13gm of fine powder was taken in a clean *Khalvayantra*.

- For Group A, B and C sufficient quantities of *Dadhi*, *Madhu* and *Palala* were added respectively, until

- *Madanaphala* which were ripen, undamaged, not very green, of pale colour were collected from Dhamane forest, Kolhapur district, Maharashtra in the month of April 2024.
- After cleaning, fruits were wrapped in *Kusha*, smeared with cow dung and dried in shade.
- After drying, *Kusha puta* were stored in heap of husk of *Godhuma* for eight days.
- After eight days, fruits developed good aroma like that of honey, then which were taken out and seeds were separated.
- Further, *Madanaphala pippali* was given *Bhavana* with *Dadhi*, *Madhu* and *Palala* individually for 3 different groups, for 4th group *Bhavana* given with all three in the same sequence.
- These processed *Madanaphala pippali* was sent for phytochemical analysis and following result was obtained.

complete soaking of the *Madanaphala Pippali*. Trituration was done until the mixture becomes dry (*Madhu bhavita dravya* did not dry completely due to the hygroscopic and high viscous nature of honey).

- For group D *Bhavana* was given with each of *Dadhi*, *Madhu* and *Palala* sequentially. The prepared *Bhavita Madanaphala Pippali* was used as *Vamana Aushadhi* on next day.
- **Drug dose-** As mentioned in *Sushruta Samhita*, 1 *Aksha Pramaṇa* is recommended for *Vamaka Yoga*. Based on this, the dosage of *Bhavita Madanaphala pippali yoga* was administered as 8-9gm, 10-11gm and 12-13gm, according to the *Koṣṭha* of the individual subjects.

Pradhana Karma

Vamana Karma

- *Akantha pana* - *Ksheera* (upto 1.0-1.5 liters).
- *Madanaphala Pippali Yoga* (based on *Koṣṭha* ranging from 8-13gm)

Group A- *Vamana* with *Dadhi bhavita Madanaphala pippali*

Group B- Vamana with Madhu bhavita Madanaphala pippali

Group C- Vamana with Palala bhavita Madanaphala pippali

Group D- Vamana with Dadhi, Madhu and Palala bhavita Madanaphala Pippali

- Bhavita Madanaphala pippali was mixed with Yastimadhu (2gm), Vacha choorna (1gm), Saindhava Lavana (1gm), Madhu (QS), made into small pills and given to subjects to swallow with little quantity of milk.
- Yastimadhu Kashaya (2-3Litres) was administered as Vamanopaga dravya.
- Every time, number of Vega, nature of vomitus was noted.
- Lukewarm Saindhava jala was administered after Yastimadhu kashaya pana.
- Procedure was continued till the appearance of Pittanta lakshanas like appearance of Pitta, Katu-Tikta Asyata, Kanta daha.
- Time was noted at each step of the procedure.

Paschat Karma

- After the completion of the procedure, Sheetajala sechana was done.
- Gargling with hot water was advised.
- After 15 minutes of rest, Dhumapana with Haridra varti was given.
- Based on Pravara, Madhyama and Heena Shuddhi, Samsarjana Krama was advised for 5, 3 and 2 days respectively.
- Peya, Vilepi, Mudga, Yusha and Mamsarasa were advised for 3, 2 and 1 meal time for Pravara, Madhyama and Heena Shuddhi respectively.

Study Duration

Treatment duration- 15 days

Follow up period- 30 days

Total study duration - 45 days

Assessment Criteria

The assessment was done based on following subjective and objective parameters.

Table 3: Subjective and objective parameters of the study

Subjective Parameters	Objective Parameters
Fatigue	TSH value
Dry skin	BMI
Loss of appetite	
Constipation	

The subjective and objective parameters were assessed and compared on (except thyroid profile)

- Before treatment on 0th day.
- After completion of treatment on 16th day.
- Follow up on 45th day.

Thyroid profile was assessed before treatment and on day of follow up.

- Both subjective and objective parameters were given with suitable grading, evaluated and statistically analysed before and after the treatment and after follow up.

Grading Chart

Table 4: Fatigue and Dry Skin

S. No	Assessment Criteria	Assessment Criteria	Grade
1	Fatigue at rest	Dryness persists even after oil application	3
2	Fatigue on mild work	Dryness relieved by oil application	2
3	Fatigue on moderate work	Dryness after bath only	1
4	Fatigue on excessive work	No dryness	0

Table 5: Loss of Appetite and Constipation

S. No	Assessment Criteria	Assessment Criteria	Grade
1	Complete loss of interest in food	Irregular for more than 2 days	3
2	Irregular food habits	On alternate days	2
3	Quantum of food decreased	Daily but hard stools	1
4	Good appetite	No constipation	0

RESULT

- **Effect on fatigue:** Within groups showed statistically significant results with a p-value of <0.05 . When comparing the efficacy of the treatment between the groups, the result was statistically insignificant, with a p-value of >0.05 , indicating that there was no significant difference between the groups in the reduction of fatigue. However, in group-A there was an overall reduction of Fatigue by 77% after follow-up, in group-B, C and D the reduction was 66.6%.
- **Effect on Dry skin:** However, in group-A there was an overall reduction of Dry skin by 50% after follow-up, in group-B the reduction was 62.5%, in group-C and D the reduction was 50%.
- **Effect on Loss of appetite:** in group-A there was an overall improvement of 66.6% after follow-up, in group-B 58.33%, in group-C 53.85% and group-D 66.6%. On comparing the efficacy of treatment
- between the groups showed statistically significant result with P value of > 0.05 .
- **Effect on Constipation:** The intervention effect on loss of appetite in group A and D with overall improvement of 75%, in group B and C 100%.
- **Effect on TSH levels:** The treatment showed a highly significant reduction in TSH levels in all the 4 Groups, group A and D with overall improvement of 49.33%, Group B 36.11% and group C 38.43%. However, the intergroup comparison yielded a p-value >0.05 , indicating no statistically significant difference in outcomes between the groups.
- **Effect on BMI:** The BMI assessment showed statistically significant in all the groups and between the group improvement with a p-value <0.05 . Group-A recorded an overall decrease in BMI of 2.08%, group-B 2.91%, group-C 3.40% and group-D 2.09%.

Overall effect of the treatment**Table 6: Result of Group A and B**

S.No	Parameters	Group A				Group B			
		Mean Score		Overall Improvement (%)	P value	Mean Score		Overall Improvement (%)	P value
		BT	AF			BT	AF		
1	Fatigue	0.90	0.20	77.7	<0.05	0.60	0.20	66.6	<0.05
2	Dry skin	0.20	0.10	50	>0.05	0.80	0.30	62.5	<0.05
3	Loss of Appetite	0.30	0.10	66.6	<0.05	1.2	0.50	58.3	<0.05
4	Constipation	0.80	0.20	75	<0.05	0.40	0.00	100	<0.05
5	TSH Value	15.59	7.90	49.3	<0.05	10.19	6.50	36.11	<0.05
6	BMI	31.62	30.9	2.08	<0.05	26.10	25.34	2.91	<0.05

Table 7: Result of Group C and D

S. No	Parameters	Group C				Group D			
		Mean Score		Overall Improvement (%)	P value	Mean Score		Overall Improvement (%)	P value
		BT	AF			BT	AF		
1	Fatigue	0.60	0.20	66.6	<0.05	0.90	0.20	66.6	<0.05
2	Dry skin	0.30	0.10	50	>0.05	0.20	0.10	50	>0.05
3	Loss of Appetite	1.30	0.60	53.8	<0.05	0.30	0.10	66.6	<0.05
4	Constipation	0.30	0.30	100	<0.05	0.80	0.20	75	<0.05
5	TSH Value	21.70	13.36	38.43	<0.05	15.59	7.90	49.33	<0.05
6	BMI	28.50	27.83	3.40	<0.05	31.62	30.96	2.09	<0.05

DISCUSSION

- The comparative analysis of the treatment outcomes across the 4 Groups showed a p-value >0.05, signifying that there was no statistically significant difference.
- However, when analyzed in terms of percentage improvement, all four groups showed encouraging clinical benefits. Group-A exhibited 53.45% improvement, Group-B 54.4%, Group-C 52.04% and Group-D 51.6% improvement.
- This suggest, although variations were observed in the extent of improvement, due to *Bhavana* of *Madanaphala pippali*, minor solubility changes may occur, but insufficient to change the clinical effect. Statistical insignificant may reflect insufficient sample size to detect small differences clinically.
- In assessing *Vamana karma* considering *Vega* initiation, number and nature of *Vega* and *Pittanta*, no single group demonstrated superiority over the others in terms of overall effect.
- Processing would have led to chemical stabilization and higher bioavailability of active saponins inspite of varied saponin percentage in the different *Bhavita Madanaphala pippali*, however stronger impact of dietary regimen, *Koshta*, *Snehapana*, *Dosha utklesha*, *Rogi bala* and *Satva* might have overshadowed the subtle pharmacological difference created by extra *Bhavana*.
- Hence, all four groups showed notable and uniformly evident clinical improvement, the difference among them was not statistically significant, indicating each group was equally effective.
- The intervention produced statistically and clinically significant improvements within the groups in all the subjective and objective parameters. Group-A exhibited 53.45% improvement, Group-B 54.4%, Group-C 52.04% and Group-D 51.6% improvement.
- The overall analysis of the treatment outcomes revealed statistically insignificant difference between the groups, with minimal variation in clinical improvement. As there was no significant difference in the effect of single or sequential *Bhavita Madanaphala pippali* on *Vamana karma*, any one *Bhavana Dravya* - *Dadhi*, *Madhu* or *Palala*- may be selected, as all are equally effective.
- *Bhavana samskara* may have contributed to the chemical stabilization and enhanced bioavailability of saponin. Despite of variation in their percentage, the content remained within the optimal range across the four groups, which may account for the similar *Vamana* effect.
- Therefore, there is no difference in the efficacy of *Vamana karma* using *Madanaphala pippali* processed with *Dadhi*, *Madhu* and *Palala* as *Bhavana dravyas*.

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CONCLUSION

- *Vamana Karma* is one of the prime *Shodhana* therapies and most effective therapeutic approach for the treatment of *Kaphaja* disorders. Hypothyroidism is an endocrine disorder marked by reduced thyroid hormone production, can be correlated with *Kaphaja Galaganda* due to *Kapha-Vata* vitiation and *Sthana vishesha*. Here, *Vamana karma* aids in expelling the vitiated *Kapha Dosha*, correcting the underlying pathology and restores normal thyroid function.
- The present study primarily focused on analysing the saponin content in various *Bhavita Madanaphala pippali*, as it is a main emetic principle constituent. Phytochemical analysis of *Madanaphala pippali* showed different saponin percentage. The saponin content was found to be comparatively lower in all the samples after *Bhavana*. Although variations in saponin contents were observed among different *Bhavita Madanaphala pippali*, no marked variation was seen in their effect on *Vamana karma*.

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