

Original Article

Anti-obesity and Anti-hyperlipidemic activity of Processed Honey - A Randomised, Open labeled, Controlled Clinical Study

Satish Pai*, Chetana Bhadrappura Shivappa¹, Aparna Surendra²

* Associate Professor and Head, Dept. of Dravyaguna, ¹PG Scholar, Department of Dravyaguna Vijnana, ²Physician, Department of Naturpathy and Yoga, JSS Ayurveda Medical College, Lalitadripura Road, Mysuru, Karnataka, India

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Address for Correspondence:

Dr. Satish Pai

Associate Professor and
Head, Dept. of
Dravyaguna, JSS Ayurveda
Medical College,
Lalitadripura Road,
Mysuru, Karnataka, India

Email:

satishayurveda@gmail.com

Abstract

Background: Obesity is a medical condition in which excess body fat is accumulated to the extent that it may have a negative impact on life of an obese patient. *Sthoulya* (Obesity) is an excessive deposition of *Medodhatu* (adipose tissue) in the body. *Madhu* (Honey) processed with *Triphala Kashaya* (decoction of Three *Myrobalans*) has been studied for its anti-obesity and anti-hyperlipidemic activity on experimental models.

Objectives: To evaluate the anti-obesity and anti-hyperlipidemic activity of processed honey and to compare its efficacy with unprocessed honey and lifestyle (diet and exercise) management on obesity.

Materials and Methods: 90 obese individuals were randomly allocated into 3 groups consisting 30 subjects in each group and were managed with lifestyle management (Diet and exercise), unprocessed honey and processed honey respectively for the period of One *Mandala Kala* (48 days). Body weight, Body Mass Index, Waist Hip Ratio and Lipid profile were considered as assessment parameters.

Observations and results: Significant reduction was noticed in unprocessed and processed honey treated groups with respect to all parameters (Body weight, Body Mass Index, Waist circumference, Hip Circumference, lipid profile), whereas Group A, which was only managed with lifestyle modification exhibited better response only with respect to body weight and BMI.

Conclusion: Processed honey has better anti-hyperlipidemic and anti-obesity effects, which can be suitably adopted along with lifestyle modification in obese individuals.

Keywords: *Anti-hyperlipidemic activity, Body mass index, Lipid Profile, Obesity, Processed Honey, Triphala Kashaya, Waist Hip Ratio*

QR Code



Citation

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Introduction

Obesity is a lifestyle disease and according to the WHO, obesity is one of the commonest and neglected conditions among both developed and developing countries. [1] Over the past two decades there is a drastic rise in the prevalence of obesity throughout the globe. By 2014, almost 30% of the worldwide population was overweight and 5% of the deaths worldwide were owing to obesity. On the off chance that the frequency proceeds along these same lines, half of the world's population will be overweight or obese by 2030. [2] Obesity is most often associated with a higher risk of mortality and morbidity, as it is an important risk factor of non-communicable diseases like cardiovascular diseases, ischemic heart disease and diabetes mellitus. [3]

Obesity and hyperlipidemia are correlated with *Sthoulya* and *Medoroga* respectively [4] and is defined as *Meda Eva Upacheeyate Shaareeram* (excessive accumulation of fat mass) [5] and is frequently accompanied by hyperlipidemia. [6] In an obese individual, adipose tissue becomes dysfunctional and leads to reduced insulin sensitivity. [7] Insulin resistance and Type 2 Diabetes mellitus are associated with dyslipidaemia. [8] Classical literature cites about the involvement of *Medodhatu* in *Sthoulya*. [9]

Management of obesity involves diet and pharmacotherapy in both Ayurveda and conventional sciences. *Sthoulya* is managed with *Guru-Atarpana* (depleting) *Chikitsa* involving *Lekhaneeya* (which removes excess *Medas*) and *Medohara Dravyas* (which reduces excess *fat*). [10] *Purana Madhu* (aged for more than a year) is one such important drug used in the management of *Sthoulya* [11] where as *Pakwa* or *Samskaritha Madhu* with *Triphala Kashaya* is specifically indicated in *Sthoulya*. [12] Debate on processing of honey by using heat is long standing issue since Samhita era. But Kaiyadeva Nighantu, strongly recommends *Pakwa Madhu* (either processed with water or selected *Dravyas*) depending upon conditions including *Sthoulya*. [13]

Processed honey (with water and *Triphala Kashaya*) has been already evaluated for its anti-obesity and anti-hyperlipidemic activities on experimental animals with positive outcome [14] and clinical trial becomes a primary pre-requisite to assess the efficacy on humans. With this perspective, the study was undertaken for clinical evaluation of processed honey in comparison with unprocessed honey and life style management.

Methodology

Deseeded fruits of *Triphala* i.e. *Hareetaki* (*Terminalia chebula* Retz), *Vibheetaki* (*Terminalia belerica* Retz) and *Amalaki* (*Embllica officinalis* Geartn) were procured from local market and authenticated by comparing with voucher specimens maintained in Department of Dravyaguna, JSS Ayurveda Medical College, Mysuru, Karnataka. Honey was procured from LAMP'S Society, Balagadi, Koppa, Chikmangaluru District and stored in stainless steel containers for aging for one year and the same was used for the study.

Deseeded fruits of *Triphala* were mixed in equal proportions (by volume) and pulverized to obtain coarse powder and fine powder. Coarse powder was used for preparation of *Kashaya* and fine powder was used for physicochemical and pharmacognostical analyses. Unprocessed and processed honey samples were analyzed for physico-chemical parameters.

Preparation of trial drug:

Triphala Kashaya was prepared as per Standard protocol. [15] *Madhupaka* was carried out by adding equal quantities of *Triphala Kashaya* and *Madhu* in a vessel and heated over *Mandagni* (Low flame) until *Paka Lakshanas* (Perfection parameters) were obtained as per standard protocol. [12] After ascertaining temperature, packaging was done using food grade plastic containers and stored.

Ethical aspects:

Ethical clearance was obtained from institutional ethics committee prior to the clinical trial (01D/2015). Informed consent forms in both regional and English language was prepared, consisting of details regarding the duration, medication of the study and explained to the study subjects and their guardians before the commencement of the study before taking consent.

Clinical study:

Study design: Randomised, open labeled, controlled clinical study

Sample size: 90 subjects

Study duration: 48 days (One *Mandala Kala*)

Drug dosage: One *Pala* (48 g) in 2 divided doses in the morning and evening hours (on empty stomach)

Anupana: *Ushnodaka* (Luke warm water)

Inclusion criteria:

- ~ Subjects having signs and symptoms of obesity with BMI more than 30 kg/m²
- ~ Subjects aged between 16-60 years and
- ~ Subjects of either gender

Exclusion criteria:

- ~ Obesity associated with systemic disorders like hypertension and diabetes mellitus
- ~ Subjects with obesity due to secondary causes and of drug induced etiology
- ~ Pregnant and lactating women

Randomization and Grouping:

90 subjects diagnosed with Obesity (BMI > 30 Kg/m²) [16] were selected for the study and randomly allocated into three groups consisting 30 subjects in each. Same diet and exercise was advised to all the subjects (Diet and exercise charts are elaborated in Table no. 1 & 2 respectively). Group A was managed with only diet and exercise, Group B with unprocessed honey whereas Group C was treated with processed honey (*Tripahala Kashaya*).

Assessment parameters:

- ~ Body weight (measured in Kg)
- ~ Body mass index (Kg/m²)
- ~ Waist circumference (in cm)
- ~ Hip Circumference (in cm)
- ~ Waist Hip Ratio
- ~ Lipid profile: Serum Total Cholesterol, Serum Triglycerides, Serum LDL, Serum, HDL and VLDDL

Collection of data: Data was collected before intervention, day 15 and Day 48 pertaining to Body weight, BMI, Waist circumference and Hip circumference whereas Lipid profile studies were conducted before intervention and after 48th day.

Statistical analyses: Data were tabulated using MS Excel Worksheets and subjected for repeated measures of ANOVA, ANOVA with Post hoc and paired samples T-test using the SPSS Software developed for Windows (version 16.0)

Table no. 1- Diet chart

Time	Food to be consumed	Quantity	
Empty stomach	Unprocessed honey with lukewarm water/ Processed honey with lukewarm water for Group B & C Only Lukewarm water for Group A	15ml Honey (Processed/ unprocessed) Lukewarm water- 50ml	
8 am	Ragi Gruel Or Green gram sprouts	150 ml	
	+ Fenugreek sprouts Or Papaya Fruit bowl	6 TSF + 6 TSF	
	+ 100g		
11 am	Tender coconut water Or Mixed Vegetable soup Or Carrot soup	150 ml	
	1pm	Red rice with vegetables curry Or Ragi ball with Vegetables Curry Or Chapathi with Boiled vegetables	1 bowl (150 g) 1 ball (size that can be held in one's palm) 2
		5 pm	Barley Gruel
Fruits-150g/			150g
Raw Veg salad- 100g /	100g		
carrot soup	150ml		
Steamed pulses and Green tea	100g 100 ml		
7 pm	Unprocessed honey with lukewarm water/ Processed honey with lukewarm water for Group B & C Lukewarm water for Group A	15ml Honey (Processed/ unprocessed) Lukewarm water- 50ml	
8 pm	Moong dal soup Or	150 ml	
	Ragi ball with Vegetables Curry Or	1	
	Vegetables Salad	150 gm	

Observation and Results

Physicochemical results of *Triphala* and honey (both unprocessed and processed) are given in Table no.3 and 4 respectively.

Table no.3: Showing results of physicochemical analysis of *Triphala*

Sl no	Test	Result	Standard
1	Foreign matter	Absent	-
2	Total ash	2.96%	Not more than 10.2 %
3	Acid insoluble ash	0.14%	Not more than 2 %
4	Water soluble ash	2.04%	Not more than 5 %
5	Water extractive value	39.2%	46 % w/w
6	Moisture content	7.1%	12 % w/w

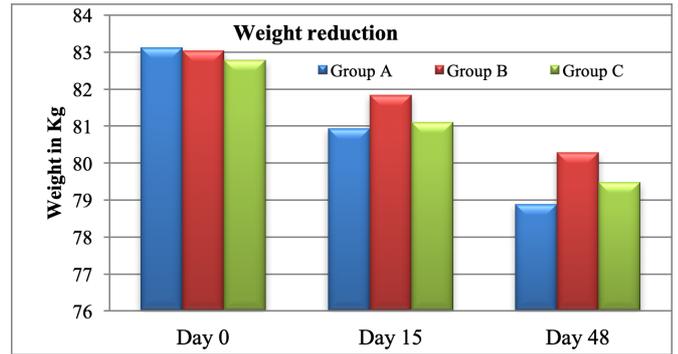
Table 4-Showing results of physicochemical analysis of honey (Both processed & unprocessed)

Sl no	Test	Unprocessed Honey	Processed Honey
1	Specific gravity	1.3826%	1.3879%
2	Moisture content	22.2%	21.6 %
3	Acidity	0.05%	0.15%
4	Viscosity @ 28 ^o C	427.79%	651.6%
5	HMF (Hydroxy methylfural) content	6.58 mg/Kg	37.02 mg/Kg

Observations with respect to

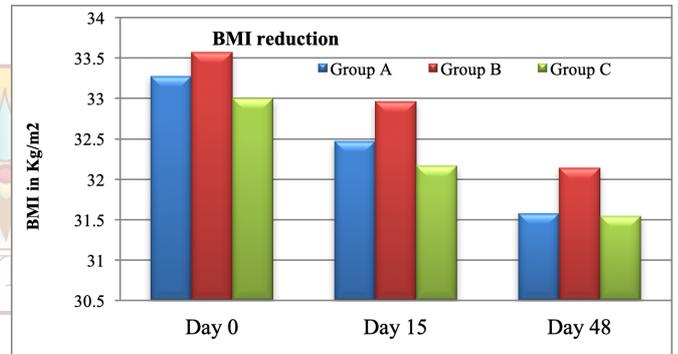
Body weight: Body weight was reduced in all the treated groups. Group A recorded highest reduction with a mean reduction of 4.226 Kg which is statistically highly significant (P < 0.001). Whereas Group C and Group B recorded mean reductions of 3.2967 Kg and 2.75 Kg respectively which is statistically significant (P<0.05) (Graph no.1).

Graph no.1: Showing weight reduction



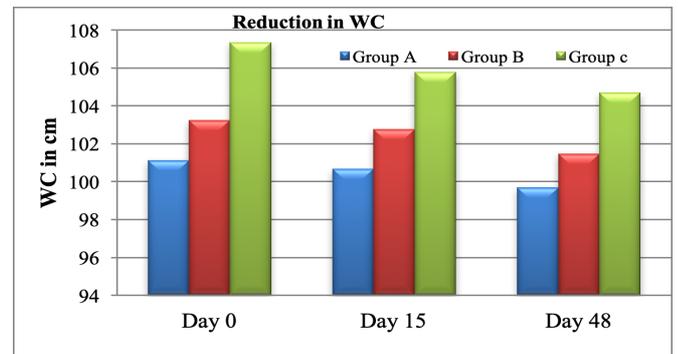
Body Mass Index: Same trend as that of body weight was followed and Group A recorded highest reduction with a mean reduction of 1.7kg/m² which is statistically significant (P<0.01) (Graph no.2).

Graph no.2: showing reduction in BMI



Waist circumference: Reduction in Waist Circumference was observed in all the treated groups. Group C recorded the highest reduction with a mean reduction of 2.6667cm which is found to be statistically significant (P value < 0.05) (Graph no. 3). Same trend was followed in the reduction of Hip circumference (WC) (Graph no. 4) and waist hip ratio (WHR).

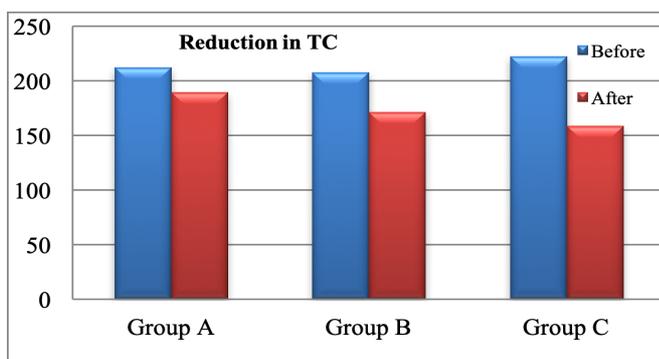
Graph 3: Waist circumference



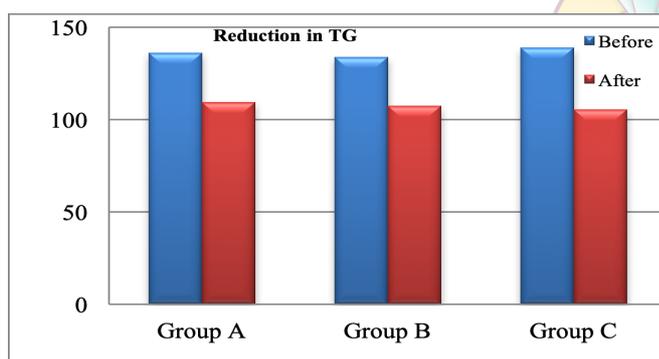
Effect on Lipid profile:

Lipids i.e. Total cholesterol, Serum Triglycerides, Serum LDL and VLDL levels were reduced in Group C whereas Serum HDL concentration remained under normal limits in all groups. HDL concentration in Group C was comparatively high and was statistically highly significant ($P < 0.001$) in Group C (Processed honey treated group). (Graph no.5-9)

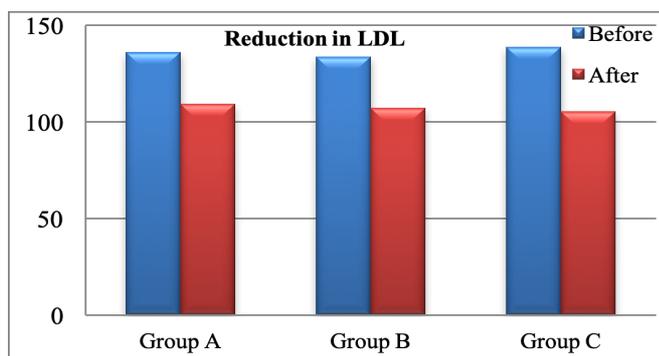
Graph no.5: Total Cholesterol



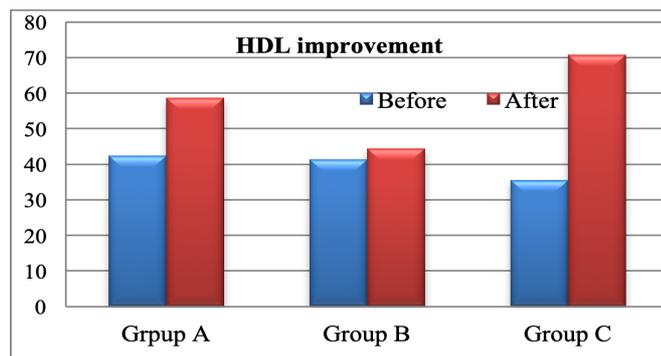
Graph 6: Serum Triglycerides



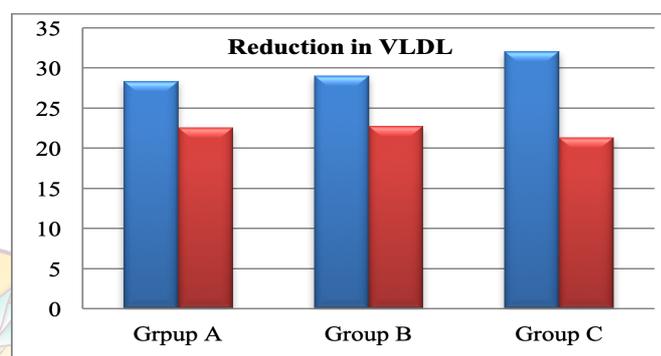
Graph 7: Serum LDL



Graph 8: Serum HDL



Graph 9: Serum VLDL



Discussion:

Generally, honey is not considered as safe product for kids and infants due to presence of microbial spores. [17, 18] Probably such incidents might have prompted honey processing during medieval period. Information about heated honey is constrained up to Caramelization of sugars and rise in HMF (Hydroxymethylfurfural) content, which happen on prolonged storage or heating of honey. [19] Analytical studies conducted previously have demonstrated that there will not be much increase in HMF content on heating honey up to 95^o C. [14]

Madhu is used both as food and medicine [20] and hence exact dosage of honey should be decided by *Yukthi* (knowledge) of a physician. Textual references perpetually refer to the use of *Triphala* and *Madhu* in the management of *Sthoulya* either separately or together. *Madhu* with drugs having similar qualities may additionally potentiate alluring impacts as *Madhu* is said to have synergistic action when utilized along with different substances according to prior investigations carried out. [14] This quality can be ascribed to the idea of *Yogavahitwa* (Synergism) of *Madhu* depicted in treatises. [21] This might be the explanation behind utilization of *Madhu* with *Triphala Kashaya* in *Sthoulya*.

Though animal studies conducted previously (by the same investigator) based on classical literature pertaining to *Madhupaka Vidhi* have established *Medohara Karma* by *Triphala Kashaya Samskarita Madhu* (processed honey), it becomes very essential to assess the role of *Samskarita Madhu* clinically because Clinical trials are the essential research tools which are considered to be “gold standard” for assessing the effects of therapy or intervention under specific controlled conditions. [22-27]

Honey was stored for a year and was used for the study. Hydroxymethylfurfural content of honey remained well within 40mg/Kg which is considered to be honey of superior quality according to FSSAI standards [28] and hence same honey sample was used for the trial. Physical activity in combination with dietary restriction has been suggested as an important component for successful weight loss regimens, [29] and therefore advised for the subjects of all groups during study period. Processed honey looks like *Avaleha* (Medicated semisolid preparation) and general dosage of *Avaleha* is one *Pala* i.e. 48g /day and the same were considered as the dosage. Study carried out for 48 days (One *Mandala*) is by all accounts suitable as there is no exact reference with respect to treatment span in Ayurvedic literature.

Weight and BMI were significantly reduced in all the groups. But comparatively, Group A had recorded highest reduction followed by Group C and Group B. It is noteworthy to mention here that restricted food intake also causes depletion in tissue mass including adipose tissue, which leads to overall reduction in body weight and hence cannot be considered as the independent factor of anti-obesity treatment assessment. [30] BMI is not an indicator of relationship between weight and muscle mass, bone weight or visceral organ mass. Individuals with a similar BMI can vary in their abdominal fat mass by virtue of the above said factors. A study concluded that compared to BMI, waist circumference and waist hip ratio are better markers for body fat in adults at the population level and are better indicators of risk factors for obesity induced complications. [31] Intra-abdominal fat is considered to be the most clinically relevant type of fat in humans. [32] In present study, Group C subjects had significant reduction in Waist and hip circumferences, which signifies that the trial drug is capable of reducing the risks of obesity induced complications.

Gallic acid or 3, 4, 5-trihydroxybenzoic acid, is a secondary plant metabolite found in higher plants, [33] honey, [34, 35,] and *Triphala* [36, 37, 38] as well. Gallic acid is known for antioxidant activity [39] and its anti-obesity properties. [40] Milliard reaction is the interaction between proteins and sugars of honey, during storage as well as processing. By-products of Milliard reaction are said to bring desirable therapeutic effects [41-44] as milliard reaction products have been shown more antioxidant property. [45] Many studies have shown that antioxidant activity strongly correlates with the content of polyphenols and that the antioxidant activity of dark honey is higher than that of the lighter ones. [46] In the present study, honey appeared darker in colour and more viscous after processing. This was perhaps because of the total polyphenols of *Triphala Kashaya* in honey media that too was processed by applying heat. Lipid profile which include Total cholesterol, Triglycerides, HDL, LDL and VLDL are maintained within normal range in both processed and unprocessed honey treated groups, where as in processed honey treated group, cholesterol concentration was observed to be comparatively lower and HDL level was comparatively higher. These findings also suggest the preventive aspect of both the drugs besides their curative nature. Thus daily consumption of *Madhu/ Triphala Kashaya/ Samskaritha Madhu* may restore physiological status among healthy individuals.

Studies conducted so far uncover the nutrient oligosaccharide [47] and fructose [48] contents of honey and their role in weight loss. Studies have also established that tannins and phenolics of honey have anti-nutrient effect and interfere with the digestive enzymes and prompt less assimilation of Carbohydrates, fats and proteins through gut causing reduction in body weight. [49] Thermal effects on Polyphenols is much explored topic since last decade, which showed conversion of free phenolics from their bound stage [50-53] after processing, making them absorbed well by intestinal mucosa, which might be the main reason for showing better efficacy of *Triphala Kashaya Samskarita Madhu*. Both *Triphala* and *Madhu* have been mentioned as *Ruksha gunatmaka* (dry, emaciating) [54,55] and indicated for *Kaphaja Vyadhis*. Heating process might have further resulted in to elevation of *Ruksha Guna* in *Samskarita Madhu*, resulting in reduction in accumulated fat and triglycerides. Thus, polyphenols, and their transformation on thermal application might have boosted the activity of the processed honey i.e. *Triphala Samskaritha Madhu* in the management of weight and lipid profile as well.

Conclusion

Present study thus establishes the effectiveness of processed honey (*Triphala Kashaya Samskaritha Madhu*) in weight reduction as well as to regulate blood lipid levels and can be incorporated to daily routine along with life style modification.

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