



Short Communication

Effects of medicated enema and nasal drops using *Triphaladi* oil in the management of obesity - A pilot studySarvesh Kumar Singh ^{a,*}, Preeti Swami ^b, Kshipra Rajoria ^c^a Department of Panchakarma, National Institute of Ayurveda, Jaipur, Rajasthan, India^b Department of Panchakarma, Dr.S.S.R.A.U, Jodhpur, Rajasthan, India^c Department of Panchakarma, National Institute of Ayurveda, Jaipur, Rajasthan, India

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ABSTRACT

An open label, randomized, comparative, interventional pilot study was done to assess the effect of *Lekhana Basti* (medicated enema) and *Rechana Nasya Karma* (Errhine therapy) in the management of *Sthoulya* with special reference to obesity. In the study 30 clinically diagnosed patient of either sex were randomly divided into two groups. In *Basti* group, *Lekhana Basti* in *Karma Basti* manner was given for 30 days. *Anuvasana Basti* (enema with *Triphaladi Taila*) in the dose of 120 mL and *Asthapana Basti* (enema with *Triphaladi* decoction etc.) in the dose of approximately 960 mL was given. In *Nasya* group, *Rechana nasya* on alternate days was given with *Triphaladi* (oil) in the dose of 0.5 mL per nostril for total 28 days. The patients were assessed on objective criteria such as such as weight, chest circumference, mid-arm circumference, mid-thigh circumference, triceps skin fold thickness, sub-scapular skin fold thickness, abdominal skin fold thickness, waist-hip ratio and lipid profile. It was observed that *Basti* group was a better intervention in providing relief, however there intergroup standard deviation was low on most of the variable expect the lipid profile. The results suggest that the *Nasya Karma* may be developed as a better practical approach in obesity management.

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1. Introduction

Obesity is a leading cause of death worldwide and it equally affects adults and children. In 2000, over 300 million obese adults were estimated worldwide and around 115 million people suffering from obesity-related problems were from developing countries [1]. The principle treatment of the condition is through dietary management and physical exercises. Still the success rate of long term weight reduction management is as low as 2–20%. Oral medication, Orlistat is approved for long term use, although there are chances of gastrointestinal side effects. Bariatric surgery is the most effective management at present but the high cost and associated risks compels the researchers to quest effective and safer managements.

In Ayurveda, obesity is described as *Sthoulya*. *Sanshodhana Karma* (biopurification) and *Basti Karma* (medicated enema) are described as major management approaches apart from oral

medications. High economical cost requirement, need of hospitalization, restriction and extent of time consumed are the major drawbacks of these modalities. There is still need of a better and more practical approach at large. The most convenient approach among *Shodhana Karma* is *Shirovirechana* or *Nasya Karma*. The role of *Nasya Karma* in *Sthoulya* is neither explored much and nor any study is published in Pub Med database till date. Hence the work was planned to explore the effect of *Rechana Nasya Karma* in obesity and compared against the *Lekhana Basti* (~medicated enema for obesity). Necessary approval was obtained from Institutional Ethical Committee of National Institute of Ayurveda, Jaipur, India and the trial was registered with clinical trial registry - India vide no. CTRI/2017/08/009430.

2. Methodology

2.1. Inclusion criteria

Patient of either sex aged between 16 and 70 years suffering from *Sthoulya* (Obesity) with BMI (basal metabolic index) ranging between

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30 kg/m² to 39.9 kg/m², not taking any medications for *Sthoulya* and fit for *Lekhana Basti* and *Rechana Nasya Karma* were included.

2.2. Exclusion criteria

Patients on long term steroid treatment, suffering from severe hypertension, type 2 diabetes mellitus, with evidence of renal, hepatic and cardiac involvement, pregnant women and lactating mother were excluded.

2.3. Withdrawal criteria

Severe adverse reaction and withdrawal of patient consent was the immediate withdrawal criteria.

2.4. Collection of drugs

The standardized trial drugs were prepared and provided with appropriate quality control in a single batch by the GMP certified Pharmacy of National Institute of Ayurveda, Jaipur, India.

2.5. Trial interventions

Study was conducted in two groups. Total 30 patients with 15 patients each in *Basti* group and *Nasya* group were registered. In *Basti* group, *Lekhana Basti* in *Karma Basti* manner was administered for 30 days. In *Nasya* group, *Rechana Nasya* on alternate days was administered with *Triphaladi Taila* (oil) [2] for 28 days. Details are mentioned in Table 1.

2.6. Criteria for assessment

Weight, chest circumference, mid-arm circumference, mid-thigh circumference, triceps skinfold thickness, sub-scapular skin fold thickness, abdominal skin fold thickness, waist-hip ratio and lipid profile as-serum cholesterol, serum triglyceride, high density lipoprotein (HDL), low density lipoprotein (LDL) and very low density lipoprotein (VLDL) were assessed.

3. Result

3.1. Study population

Patient's profile are detailed in Supplementary table.

3.1.1. Effect of interventions

It was observed that the *Basti* group had yield better results in most of the variables than *Nasya* group, however the intergroup standard deviation on most of the variables was low except that of lipid profile. The effect of interventions are expressed in mean and standard deviations (S.D.) in Table 2.

3.2. Safety and tolerability

All the registered patients had completed the study. No abnormal laboratory results or adverse events were reported.

4. Discussion

Excessive intake of *Madhura Ahara* (~high glycemic index food) & *Guru-Snigdha Kaphavardhaka Ahara* (*Kapha* promoting diet), *Adhyashana* (overeating), *Avyayama* (sedentary life style), *Divas-wapa* (habit of day nap) *Achinta* (care free attitude) and *Harsh* (exhilaration), causes obstruction of *Srotas* (channels) by *Meda* (~adipose tissue), vitiates *Vata Dosh*a in *Kostha* (~organs with hollow

cavity) and flares up the *Agni* (~digestive power). This causes overeating and over production of *Rasa* and *Mala Rupa Meda Dhatu* (~low and very low density lipoprotein) leading to *Sthoulya*. The line of treatment for *Medajaroga* (~diseases occurred in vitiated fatty tissue) is use of *Vataghna* (pacifying *Vata dosha*), *Shleshma-Medohar* (reduction of *Kapha dosha* and fatty tissue), *Ruksha-Ushna-Tikshna Basti* (enema with drugs having rough, hot potency and penetrating properties), *Ruksha Udvartana* (rubbing with dry powder and paste), *Triphala*, *Takrarishta*, honey, *Bilvadi Kwath* (decoction), *Panchamoola* (roots of 5 plants), *Shilajatu* (black bitumen) etc. [3].

Thus following the prescribed line of treatment *Lekhana Basti* (enema with medicated decoction) prepared from *Lekhaniya Mahakashaya* (a combination of 10 drugs having scraping properties) was used. It breaks the *Srotosanga* (obstruction at micro channel level) with *Tikta*, *Katu* and *Kashaya Rasa* (nutrients with bitter, pungent and astringent taste), causes *Shoshanna* (emaciation), *Lekhana* (scraping), *Amahara* (removal of undigested food) *Karma* (work/activity), *Deepana* (appetizing) and *Pachan* (digestive) *Karma*. It works at the level of *Agni* (digestive and transforming activities up to cellular level) and corrects the *Medo Dhatvagni-mandhya* (improper metabolic activities at adipose tissue level) and checks the progression of *Meda Sanchaya* (accumulation of adipose and other fatty tissue) by preventing the formulation of *Meda*. *Anuvasana Basti* with *Triphaladi Taila* is helpful in regulating the vitiated *Vata Dosh*a.

In *Sthoulya Chikitsa*, *Acharya Chakrapani* had mentioned that *Nasya Karma* using *Triphaladi Taila* as corrective measure for obesity. Thus the present study was taken to explore the role of *Nasya* in management of *Sthoulya*. *Triphaladi Taila Rechana Nasya* was administered on alternate day as the standard textual protocol of *Nasya Karma*. The *Triphaladi Taila* possesses *Ushana*, *Tikshana*, *Katu*, *Tikta* and *Kapha-Vata Shamaka* (pacifying) properties. The potency of the drugs on administration through nostrils reaches *Shringataka* (~vital point at the base of nose) and spreads into the *Murdha* (Brain), *Netra* (eyes), *Shrota* (ear), *Kantha* (throat), *Sir-amukhas* (opening of the vessels), etc. and assist in expelling the morbid *Doshas* from the body [4]. The probable mode of action of *Nasya Karma* may be attributed due its stimulating effect on brain through olfactory and respiratory pathway. The nasal epithelium is a highly permeable monolayer, the sub mucosa is also richly vascularized thus promotes rapid absorption and provides direct entry of drug into systemic circulation and avoids hepatic first-pass metabolism [5]. Studies have suggested intranasal drugs delivery via olfactory and respiratory pathways a promising option to provide medication to central nervous system [6,7]. Additionally lipid based drugs of lower molecular weight less than 400–600 Da (Dalton) with positive charge have better capacity to cross the blood brain barrier [8]. The hypothalamus of the central nervous system is a prime area influencing the appetite and gut hormones. The hypothalamic arcuate nucleus regulates appetite through pro-opiomelanocortin appetite-inhibiting neurons, neuropeptide Y and agouti-related peptide appetite-stimulating co-expressing neurons [9]. A pilot study had also demonstrated the effect of intranasal spray of oxytocin (8 week treatment) in providing substantial weight loss in obese or overweight adults [10,11]. Thus *Nasya Karma* may have affect the hypothalamus like the oxytocin spray which resulted in decreased caloric intake, enhance insulin sensitivity and fat oxidation.

The prime limitation of the study was the small sample size which leads to limitation of statistical analysis. We have observed the minimal changes in lipid profile in some of post menopausal women in both study groups. These cases may need longer courses of Panchakarma procedures for better result. In future multicenter study of larger samples may be planned to conceal the effect of factors like *Prakriti* (body constitution), *Desha*

Table 1
Details of Trial interventions.

Intervention	Basti group	Nasya group
	Karma Basti	Rechana nasya
Place of administration	The Basti was prepared (individually for each patient) and administered in P.G Department of Panchakarma by the Post graduated scholars.	The Nasya karma was administered in P.G Department of Panchakarma by the Post graduated scholars.
Dosage regimen and quantitative description	Karma Basti was given for 30 days. i.e. 1 Anuvasana Basti (dose – 120 mL) in the beginning and 5 at the end with 12 Asthapana (dose – 960 mL) and 12 Anuvasana Basti on alternate days was administered for 30 consecutive days.	Rechana Nasya on alternate days was given in the dose of 8 drops (0.5 mL) per nostril for total 28 days.
Drugs	Asthapana Basti - <i>Musta</i> (<i>Cyperus rotundus</i> Linn.), <i>Kushtha</i> , (<i>Saussurea costus</i> (Falc.)Lipsch), <i>Haridra</i> (<i>Curcuma longa</i> Linn.), <i>Daruharidra</i> , (<i>Berberis aristata</i> DC.), <i>Vacha</i> (<i>Acorus calamus</i> Linn.), <i>Ativisha</i> (<i>Aconitum heterophyllum</i> wall.), <i>Katukarohini</i> (<i>Picrorhiza kurroa</i> Royle ex. Benth), <i>Chitraka</i> (<i>Plumbago zeylanica</i> Linn.), <i>Chirbilva</i> (<i>Holoptelea integrifolia</i> Planch), <i>Madhu</i> (Pure raw honey), <i>Saindhava</i> (pure rock salt), <i>Sarshapa taila</i> (oil of <i>Brassica campestris</i> Linn.), <i>Gomutra</i> (fresh cow's urine), <i>Yavakshara</i> (<i>Hordeum vulgare</i> Linn.), <i>Yavani</i> (<i>Trachispermum ammi</i> Linn.), <i>Madanaphala</i> (<i>Randia dumetorum</i> Retz.), <i>Bilva</i> (<i>Aegle marmelos</i> Linn.), <i>Satavari</i> (<i>Asparagus racemosus</i> Wild.), <i>Pippali</i> (<i>Piper longum</i> Linn.) Anuvasana Basti – <i>Triphaladi Taila</i> Nirhu Basti - <i>Yavakuta</i> (coarse powder) of <i>Lekhana Basti Kwath Dravya</i> (100 g) and was boiled in 1600 ml of water, reduced to 400 mL and filtered. Honey (240 g) and powdered <i>Saindhava</i> (10 g) was mixed well by triturating in <i>Khalva</i> (mortar). Followed by addition of <i>Sarshapa Taila</i> (<i>mustard oil</i>) (120 mL), then <i>Putiyavanyadi Kalka</i> (80 g), then <i>Kwath</i> (400 mL) then <i>Gomutra</i> (120 mL) and <i>Yavakshara</i> (10 g) was added and mixed thoroughly. This mixture was made lukewarm by indirect heating by keeping the vessel containing the homogenous mixture of <i>Basti Dravya</i> in hot water before administration of <i>Basti</i> . Anuvasana Basti – <i>Saindhava</i> (4 g) and paste of <i>Shatahwa</i> (<i>Anethum sowa</i> Kurz.) (4 g) was mixed well by triturating in <i>Khalva</i> in 120 mL of <i>Triphaladi Taila</i> and resulting composition was filtered and indirectly heated over water bath and filled in <i>Basti Yantra</i> for administration.	Triphaladi Taila - <i>Til Taila</i> (oil of <i>Sesamum orientale</i> Linn), <i>Haritaki</i> (<i>Terminalia chebula</i> Retz.), <i>Amalki</i> (<i>Phyllanthus emblica</i> Linn.), <i>Vibhitaki</i> (<i>Terminalia bellirica</i> (Gaertn) Roxb.), <i>Ativisha</i> (<i>Aconitum heterophyllum</i> wall.), <i>Nishotha</i> (<i>Operculina turpethum</i> Linn.), <i>Chitraka</i> (<i>Plumbago zeylanica</i> Linn., <i>Vaasa</i> (<i>Adhatoda vasica</i> Ness (Syn.)), <i>Nimba</i> (<i>Azadiracta indica</i> A. Juss), <i>Aragvadha</i> (<i>Cassia fistula</i> Linn.), <i>Saptaparna</i> (<i>Alstonia scholaris</i> R. Br), <i>Haridra</i> (<i>Curcuma longa</i> Linn.), <i>Daruharidra</i> (<i>Berberis aristata</i> DC.), <i>Guduchi</i> (<i>Tinospora cordifolia</i> (Willd.)), <i>Indrayana</i> (<i>Citrullus colocynthis</i> Linn.), <i>Pippali</i> (<i>Piper longum</i> Linn.), <i>Kushtha</i> (<i>Saussurea costus</i> (Falc.) Lipsch)
Method of preparation of Basti		
Characteristics of the Basti dravya (Qualitative Testing)	The <i>Basti Dravya</i> was checked qualitatively by taking on the palm of hand. A homogenous uniform solution that neither run quickly over nor stick to palm and leaves no oil traces on the hand was considered well prepared.	
Purva karma	Asthapana Basti – The Basti was given before meals both <i>Sarvanga</i> (whole body) <i>Abhyanga</i> (Ayurvedic massage) and <i>Swedana</i> (sudation) was administered as preparatory measure. Anuvasana Basti – The patient was subjected to <i>Abhyanga</i> and <i>Swedana</i> followed by intake of meals somewhat 1/4th less than the routine diet.	<i>Nasya</i> was given before the meals both <i>Abhyanga</i> and <i>Swedana</i> of head and neck region was done as preparatory measure.
Pradhana karma	The patient is made to lie in left lateral posture with right leg semiflexed and bend towards the surface. <i>Basti netra</i> smeared with oil is gently inserted in the anal opening in parallel direction to vertebral column. The <i>Basti putaka</i> is squeezed with a constant pressure to introduce <i>Basti Dravya</i> into the anus. A small amount of liquid is retained in the <i>Putaka</i> and the <i>Basti Netra</i> is gently removed from the anus.	<i>Triphaladi Taila</i> was instilled in each nostrils in the dose of 8 drops (0.5 ml) followed by <i>Dhumapana</i> and <i>Ksharaambu Gandusha</i> .
Paschat karma	Asthapana Basti - After <i>Basti Pratyagamana</i> patient was asked to take hot water bath and to take diet containing pulse soup in lesser quantity than the routine and advised him to avoid the Loud speaking, Excessive vehicle travelling, Excessive walking, Excessive sitting, <i>Ajirna Bhojana</i> (Indigestion), Unwholesome diet, Day napping and Sexual indulgence. Anuvasana Basti – After <i>Basti administration</i> patient was asked to maintain lying position for atleast an hour and follow restriction of <i>Basti Karma</i> .	After <i>Nasya Karma</i> patient was asked to take normal diet after 48 min and advised to avoid the <i>Pariharya Visaya</i> (avoidable things) as also described in <i>Basti karma</i>

Table 2
Comparative analysis of both (Basti and Nasya) interventions.

Variables	Basti Group			Nasya Group			SD ^a
	Baseline	After treatment	Mean change (mean ± SD)	Baseline	After treatment	Mean change (mean ± SD)	
Weight	86.86	83.00	3.867 ± 1.356	79.46	78.66	0.800 ± 0.861	0.8619
Chest circumference	109.5	106.3	3.200 ± 1.821	0.703	0.703	0.703 ± 0.703	0.1817
Mid-arm circumference	35.00	33.13	1.867 ± 1.506	33.80	32.20	1.600 ± 1.183	1.183
Triceps SFT	3.187	2.713	0.473 ± 0.2815	3.200	2.620	0.580 ± 0.497	0.2898
Sub scapular SFT	3.560	2.807	0.753 ± 0.4307	3.260	3.047	0.213 ± 0.331	0.3314
Abdominal SFT	3.893	2.867	1.027 ± 0.7015	3.273	2.900	0.373 ± 0.489	0.4873
Mid-thigh circumference	61.26	58.13	3.133 ± 2.997	57.86	57.06	0.800 ± 1.082	1.082
Waist-hip ratio	0.872	0.832	0.040 ± 0.0397	0.821	0.809	0.012 ± 0.023	0.0236
HDL	48.33	47.727	0.6067 ± 3.274	47.60	45.707	1.893 ± 5.071	6.0
LDL	103.0	93.600	9.467 ± 26.478	110.5	103.85	6.680 ± 29.673	39.70
VLDL	31.17	30.124	1.049 ± 7.075	32.17	27.573	4.600 ± 13.468	15.0
Serum cholesterol	182.6	168.57	140.32 ± 31.263	187.1	182.60	4.533 ± 38.084	49.14
Serum triglyceride	156.0	150.83	5.165 ± 35.606	160.2	152.67	7.533 ± 54.273	64.8

SFT – Skin fold thickness; HDL – High density Lipoprotein; LDL – Low density Lipoprotein; VLDL – Very low density Lipoprotein; SD – Standard deviation from paired t test; SD^a – Standard deviation of Inter group comparison.

(place), *Kala* (time) etc. A similar study can be planned to explore the additive effect of *Nasya karma* after *Lekhana basti karma* in management of obesity.

5. Conclusion

The results suggests that *Nasya Karma* may be adopted as more practical approach for obesity management and may achieve similar effects as *Basti Karma*. It may also be used an additive therapy along with dietary modification, physical exercises, oral medication, *San-shodhana Karma* and *Basti Karma* in obesity management. In future the nasal route may be developed as new drug delivery route for condition similar to obesity management.

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Conflict of interest

None.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.jaim.2020.02.001>.

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