Short Communication

Effects of medicated enema and nasal drops using *Triphaladi* oil in the management of obesity - A pilot study

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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 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 approach 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...
30 kg/m² to 39.9 kg/m², not taking any medications for Shhoulya 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), Auyayama (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 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 Shhoulya. The line of treatment for Medajaroga (~diseases occurred in vitiated fatty tissue) is use of Vatagghna (pacifying Vata dosha), Shlehma-Medohar (reduction of Kapha dosha and fatty tissue), Raksha-Ushna-Tikshna Basti (enema with drugs having rough, hot potency and penetrating properties), Raksha Udvartana (rubbing with dry powder and paste), Triphala, Takrarishrata, honey, Bilvadi Kwath (deoction), 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 Lekhniya Mahakashaya (~a combination of 10 drugs having scraping properties) was used. It breaks the Srotosanga (obstruction at micro channel level) with Tikta, Katu and Kashaaya 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 Dhatvagnandhiya (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 Dosa.

In Shhoulya 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 Shhoulya. 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 that 400 (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-stimulating co-expressing neurons and 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 |
|--------------|-------------|-------------|
| 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 Anuvasaana Basti (dose – 120 mL) in the beginning and 5 at the end with 12 Asthapanaa (dose – 960 mL) and 12 Anuvasaana 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** - Musta (Cyperus rotundus Linn.), Kshitha, (Sausurea costus (Falc.,Lipsch), Haridra (Curcuma longa Linn.), Daruhariadora (Berberis aristata DC.), Vacha (Acorus calamus Linn.), Ativisha (Aconitum heterophyllum wall.), Katukarohini (Picrorhiza kurroa Roxb ex. Benth), Chitraka (Plumbago zeylanica Linn.), Chirivita (Holoptelea integrifolia Planch), Madhu (Pure raw honey), Saindhava (pure rock salt), Sarshapa taila (oil of Brassica campestris Linn.), Gomutra (fresh cow's urine), Yavakshara (Hordemum vulgare Linn.), Yavani (Trachispermum ammi Linn.), Madanaphala (Randia dumetorum Retz.), Bilva (Aegle marmelos Linn.), Satavari (Asparagus racemosus Wild.), Pippali (Piper longum Linn.) | **Triphaladi Taila** - Til Taila (oil of Sesamum orientale Linn.), Haritaki (Terminalia chebula Retz.), Amalaki (Phyllanthus emblica Linn.), Vibhistaki (Terminalia bellirica (Gaertn) Roxb.), Ativisha (Aconitum heterophyllum wall.), Nishotha (Oerculina turgurthum Linn.), Chitraka (Plumbago zeylanica Linn., Vaasa (Adhatoda vasica Ness (Syn.)), Nimbha (Azadiracta indica A. Juss.), Arogadhu (Cassia fistula Linn.), Saptaparna (Alstonia scholaris R. Br), Haridra (Curcuma longa Linn.), Duruhardra (Berberis aristata DC.), Guduchi (Tinospora cordifolia (Wild.)), Indrayana (Citrusul colocynthis Linn.), Pippali (Piper longum Linn.), Kshitha (Sausurea costus (Falc. Lipsch) |
| Method of preparation of Basti | **Anuvasaana Basti** - Triphaladi Taila | **Nasya group** |
| **Nirhu Basti** - Yavakata (coarse powder) of Lekhana Basti Kwath Dravya (100 g) and was boiled in 1600 mL of water, reduced to 400 mL and filtered. Honey (240 g) and powderied Saindhava (10 g) was mixed well by triturating in Khalva (mortar). Followed by addition of Sarshapa taila (mustard oil) (120 mL), then Patyavanyadi Kalka (80 g), then Kwath (400 mL) then Gomutra (120 mL) and Yavakshara (10 g) was added and mixed thoroughly. This mixture was made lukewarm by indirect heating by keeping the vessel containing the homogenous mixture of Basti Dravya in hot water before administration of Basti. | **Triphaladi Taila** was instilled in each nostrils in the dose of 8 drops (0.5 mL) followed by Dhmapana and Ksharaambu Gandusha. |
| Characteristics of the Basti Dravya (Qualitative Testing) | The Basti Dravya 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. | The patient was asked to take normal diet after 48 min and advised to avoid the Paradhaya Vosya (avoidable things) as also described in Basti karma. |
| **Purva karma** | **Asthapana Basti** - The Basti was given before meals both Sarvanga (whole body) Abhyanga (Ayurvedic massage) and Swedana (sudation) was administered as preparatory measure. | **Nasya was given before the meals both Abhyanga and Swedana 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. Basti netra smeared with oil is gently inserted in the anal opening in parallel direction to vertebral column. The Basti putaka is squeezed with a constant pressure to introduce Basti Dravya into the anus. A small amount of liquid is retained in the Putaka and the Basti Netra is gently removed from the anus. | **Triphaladi Taila** was instilled in each nostrils in the dose of 8 drops (0.5 mL) followed by Dhmapana and Ksharaambu Gandusha. |
| **Paschat karma** | **Asthapana Basti** - After Basti Pratyaygamana 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, Ajirna Bhojana (Indigestion), Unwholesome diet, Day napping and Sexual indulgence. | After Nasya Karma patient was asked to take normal diet after 48 min and advised to avoid the Paradhaya Vosya (avoidable things) as also described in Basti karma. |
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 as 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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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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Table 2

Comparative analysis of both (Basti and Nasya) interventions.

| Variables          | Basti Group                | Nasya Group                | SDa                |
|--------------------|----------------------------|----------------------------|--------------------|
|                    | 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   | 3.580    | 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 ± 1.062          | 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         | 4.650 ± 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; SDa - Standard deviation of Inter group comparison.

Appendix A. Supplementary data

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