Research Article

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ROLE OF LEKHANA BASTI IN METABOLIC SYNDROME: A CLINICAL TRIAL

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ABSTRACT

Background: A constellation of conditions known as the Metabolic Syndrome includes hyperglycaemia, elevated blood pressure, insulin resistance, dyslipidaemia and central obesity. The two most significant criteria for this collection are central obesity and insulin resistance. Its frequency quickly increased in the modern period and has had a significant socioeconomic impact. Finding a safe and affordable treatment for Metabolic Syndrome is urgently needed because it is one of the primary risk factors for cardiovascular disease and type 2 diabetes. In the Ayurvedic classics, Santarpana Nimittaj Vikara (diseases due to overeating) is related to Metabolic Syndrome, and Lekhana Basti (therapeutic enema with scrapping properties) appears to be an effective treatment because it is one of the fastest methods to achieve apatarpana (fasting). Objective: The objective of the study is to evaluate the role of Lekhana Basti in Metabolic Syndrome. Material and methods: Patients of either sex who fulfilled the study's eligibility requirements and were aged between 20-60 years were enrolled. Lekhana Basti was given to each of the 21 patients in the morning for 15 days, along with Matra Basti (a type of oleaginous enema) in the evening. The same method was then done after a 15-day break. The final result was then seen after 15 days. Results: In terms of the criteria for weight, waist size, blood sugar fasting, and diastolic blood pressure, the intervention is highly significant; in terms of systolic blood pressure and LDL, it is significant; and in terms of triglycerides and HDL, it is not significant. Conclusion: Lekhana Basti is an ideal therapy for Metabolic Syndrome.

Keywords: Metabolic Syndrome, Insulin resistance, Lekhana Basti, Santarpana Nimittaj Vikara, Type 2 Diabetes Mellitus

INTRODUCTION

The term "Metabolic Syndrome" refers to a collection of interrelated physiological, biochemical, clinical, and metabolic variables that directly raise the risk of Type 2 Diabetes mellitus and atherosclerotic cardiovascular disease [1, 2]. It is a cluster of at least three of the following five conditions: central obesity, hypertension, hyperglycaemia, hypertriglyceridemia, and low serum high-density lipoprotein. [3-5]. The postulated multi-factorial etiologies include dietary habits, genetic predisposition, ethnicity, etc. [6] We can say that it is a disorder in which the balance between the usage and storage of energy is disturbed.

Researchers from the University of Eastern Finland and the University of Exeter in the United Kingdom found that people's risk of developing Metabolic Syndrome doubled in people during the growth period from adolescence to young adulthood. Additionally, they discovered that men had a five-fold higher risk of developing metabolic syndrome than women did. [7] According to research, there is an increase in the prevalence of Metabolic Syndrome from 20 years old through the sixth and seventh decades of life for males and females, respectively.[8] According to Ponholzer *et al.,* postmenopausal women had a high prevalence of Metabolic Syndrome, ranging from 32.6% to 41.5%.[9]

According to the International Diabetes Federation, 25% of adults worldwide are estimated to have Metabolic Syndrome. [10] According to Framingham Heart Study research, a weight gain of less than 2.25 kg over 16 years was linked to a 45% higher chance of getting the Metabolic Syndrome. [11] The prevalence of the Metabolic Syndrome and its components is influenced by variations in genetic make-up, food, levels of physical activity, smoking, family history of diabetes, and education. [12] Worldwide, the prevalence of Metabolic Syndrome ranged from 7% to 56% in women and from 8% to 43% in males (NCEP-ATP III criteria, 2001).[12]

Since there is no established method to prevent or treat the entire syndrome, which has insulin resistance as its core component, managing Metabolic Syndrome clinically is challenging. [13] Therefore, most doctors treat each Metabolic Syndrome component independently, focusing on those that are responsive to pharmacological treatment easily. Most of the time, doctors address Metabolic Syndrome risk factors in accordance with the most recent treatment recommendations of the National Cholesterol Education Programme (NCEP).[14]

Although it isn't stated explicitly in the Ayurvedic texts, we can symptomatically correlate it to Santarpana Nimittaj Vikara, which Acharya Charaka mentioned. [15] The treatment for Santarpana Janya Vyadhi (disease) is apatarpana. When comparing all of the Ayurvedic therapy options, Basti (therapeutic enema) appears to be the best choice as when prepared with apatarpaka (causing fasting) drugs, it is one of the quickest ways to attain Apatarpana.[16] We may state that Lekhana

(scrapping) is the remedy that can eliminate unusually elevated sneha (fats). [17]

So, in light of the above references from classics, Lekhana Basti was chosen for the current study to evaluate its impact on the management of Metabolic Syndrome.

Aims And Objectives: To evaluate the efficacy of Lekhana Basti in the Management of Metabolic Syndrome.

MATERIAL AND METHODS

Ethical clearance: The research has been ethically approved by Uttarakhand Ayurved University, and the researcher is also enrolled in CTRI with CTRI number CTRI/2018/05/014339. Written consent was obtained from all the subjects before the trial, and the study was conducted in accordance with ICH GCP Guidelines.
Study design: 21 patients with Metabolic Syndrome were selected from the O.P.D. / I.P.D. Department of Panchakarma and Kayachikitsa, Rishikul Campus, Haridwar, Uttarakhand, India.
Type of Study: Single group, open-label, clinical trial with pre-post and follow-test design.
Duration of Study: 60 days.
Assessment: Done at intervals of 15 days.

Inclusion criteria (NCEP ATP III -any 3 or more out of 5)
1. Age 20- 60 years
*2. Fasting glucose > 100 mg/d1 (or receiving drug therapy for hyperglycaemia).
*3. Blood pressure > 130/85 mmHg (or receiving drug therapy for hypertension).
*4. HDL-C < 40 mg/dl in men or < 50 mg/dl in women (or receiving drug therapy for reduced HDL-C)
*5. Waist circumference >102 cm (40 inches) in men or 88 cm (35 inches) in women, if ASIAN > 90 cm (35 inches) in men or > 80 cm (32 inches) in women.
*6. Triglycerides: ≥150 mg/dl (1.695 mmol/l)
7. Patient fit for Lekhana Basti procedure [18] (* 3 or more out of 5 criteria)

Exclusion Criteria
1. Age group: < 20 years and >60 years of age.
2. Uncontrolled Diabetes Mellitus (Type 2) or with complications (Nephropathy).
3. Uncontrolled Hypertension or with complications.
4. Known case of IHD, CHF and any other vascular Disorders.
5. Patient suffering from anorectal ailments.

Written informed consent was obtained from patients before they entered the study. The importance of them for adherence to the treatment, pathya-apathya (do's and don'ts) associated with the disease, follow-up schedule, and dates for visits to the hospital was issued.

Laboratory Investigations
- Routine haematological and urine examination
- Blood sugar (Fasting)
- Lipid Profile
- Renal Function Test, X-ray Chest, E.C.G., Liver Function Test (If required)

Withdrawal criteria
- Personal matters
- Inter-current illness
- Aggravation of complaints
- The patient develops any adverse severe effect

Intervention

Methodology for Lekhana Basti
All 21 patients were administrated with Lekhana Basti. The complete Lekhana Basti procedure included Lekhan Basti in the morning for 15 days and Matra Basti in the evening. Then, after giving a 15-day interval, the same procedure was repeated. The result was observed after 15 days.

Follow-up: After completion of therapy, the patient was advised to visit OPD after one month.

Data collection methods: Pre-treatment and clinical observational data were collected from the registered patients. They were then evaluated for the chief objective parameters in the table below. The assessment was done before the initiation of the trial and at regular intervals of the procedure for 60 days. A follow-up was done after the trial had been completed for one month to look for any recurrence.

Table 1: Assessment of the Patient on the following parameters

Parameter	BT	F1	F2	AT
Weight				
Waist Circumference				
Blood Sugar (F)				
Blood Pressure				
Triglycerides				
HDL				
LDL				

BT: Before Treatment, F1: Follow Up 1, F2: Follow Up 2, AT: After Treatment.

To objectively assess therapy's effect, all the signs and symptoms were observed based on percentile.

Table 2: Assessment of the effect of therapy

Complete Remission	100% relief
markedly improved	71% - 99% relief
Moderately improved	41%-98% relief
mildly improved	16% - 40 % relief
Unchanged	0% - 15% relief
Worsened	<0%

Statistical analysis
The information collected based on the above observations was subjected to statistical analysis using Graph Pad In stat, Software version 3.10 and SPSS software. A paired- t-test was applied to the intra-group comparison of objective parameters.
Thus, the obtained results were interpreted as:

Table 3: Interpretation of results

Non-significant	P > 0.05
Significant	P< 0.05
Very Significant	P < 0.01
Highly significant	P < 0.001

OBSERVATION AND RESULTS

Pre-treatment observation
Demographic Studies:
Total Registered patients- 21
Completed the treatment -13
LAMA patients -8

Post Treatment Observation

Table 4: Effect of Intervention on Objective Parameters

Parameter	Mean		%	SD	t-Value	P-Value	Result
	BT	AT					
Weight	86.354	82.846	4.06	2.212	5.718	<0.001	HS
Waist Circumference	110.76	104.84	33.65	1.891	11.292	<0.001	HS
Blood Sugar (F)	117.07	100.80	77.37	14.08	4.164	0.001	HS
Systolic BP	132.46	127.00	82.25	5.60	3.512	<0.05	S
Diastolic BP	86.154	80.923	87.50	4.285	4.402	<0.001	HS
Triglycerides	150.37	137.99	-7.43	57.143	0.781	>0.05	NS
HDL	36.728	39.02	27.71	7.393	-1.118	>0.05	NS
LDL	120.83	93.665	79.43	39.723	2.666	<0.05	S

BT: Before Treatment, AT: After Treatment

Table 5: Estimation of overall Response of Treatment

Overall improvement	Frequency	Percentage
Complete remission	0	0.00
Marked improvement	0	0.00
Moderate improvement	3	23.08%
Mild improvement	7	53.84%
No improvement	3	23.08%
Total	13	100%

DISCUSSION

Disease

In Ayurveda, metabolism is regarded as an Agni (digestive power) function. Improper metabolism leads to Metabolic Syndrome. Many factors contribute to Metabolic Syndrome, including sedentary behaviour, fatty, high-calorie diets, excessive calorie intake, and inactivity. They predominantly vitiate Agni, particularly Medodhatvagni (fat metabolism at tissue level) and produce ama (undigested metabolic waste), Kapha (one of the three bodily humours representing water) and Meda (fat tissue). Therefore, Metabolic Syndrome is a Santarpana Nimittaj Vikara. The main features of Metabolic Syndrome, namely obesity, dyslipidaemia and diabetes, have been mentioned as the result of Medovaha sroto dusti (disturbed fat metabolism) in Ayurvedic texts.

So, we can divide and compare the progression of Metabolic Syndrome into three stages according to Ayurveda:
a) Initial stage - Medovaha Sroto dusti.
b) Middle-stage - Type 2 Diabetes mellitus and coronary artery disease, which can be called sankara vyadhi (comorbidity).
c) Later stage - Complication of specific diseases like acute pancreatitis, CAD due to hyper triglyceridemia, Diabetic retinopathy, neuropathy, nephropathy, etc. due to Diabetes mellitus and cerebral haemorrhage, hypertensive cardiomyopathy, hypertensive retino and nephro pathy due to Hypertension.

Among the sapta dhatus (the seven bodily tissues), Meda dhatu represents adipose tissue or fat. [19] Medovaha sroto dushti is caused by insufficient exercise or physical activity, sleeping throughout the day, and consuming too many sweet, fatty, or other Kapha-dosha-vitiating foods. [20] This, in turn, increases the Meda dhatu. According to Ayurveda, eating too many sweets causes them to turn into fat or sneha. [21] It causes Meda dhatu to deposit in various bodily regions, particularly over the abdomen. Abadha Meda (free-flowing fats) is produced by an abnormally increased Meda dhatu down to the cellular level. [22] It serves as a substrate for the pathogenesis of Prameha (Diabetes), including Madhumeha (Type 2 Diabetes mellitus). Due to the close similarities between the causes of Medo dhatu dushti and vitiated Kapha dosha, dhamanipratichaya (atherosclerosis) might result from vitiated Kapha dosha. [23] Its association with vitiated Meda dhatu may result in Vyanabala Vaishamya (Hypertension). Hypertension can develop as a chronic complication or associated condition with obesity. Eventually, it produces all of the symptoms of Medo roga (Hyperlipidaemia) with Vyanabalavaishamya, simulating Metabolic Syndrome. Additionally, Prameha and Atisthoulya (obesity) were explained by Acharya Charaka under santarpana janya vyadhi, along with other illnesses with comparable etiologies. [24]

Mode of action of Lekhana Basti in Metabolic Syndrome

Due to the use of diverse pharmacological combinations, the multifaceted effects of Basti are possible. [25] The specific formulation called ooshakadigana dravya (alkaline substances) mainly possesses katu (pungent), tikta (bitter) and kashaya rasa (astringent). Ushna virya (hot potency) and katu vipaka (post-digestive effect of pungent substances) have ushna (hot), tikshna (sharp), laghu (light) and rooksha (dry) gunas (quality) inherent within them. Being Tejo guna pradhana (mainly containing fire element), these properties seem to act at the level of jatharagni (main digestive fire), enhancing the dhatvagni (tissue metabolism). As a result, ama rasa (undigested/unripe bi-product) is prevented from forming, and the sequential formation of rasa (plasma) and rakta (blood) is accomplished, resulting in a decrease in the formation of Meda dhatu (fat tissues) and also causing jatharagni deepti (ignition of digestive fire). Therefore, this prevents the patient from engaging in the causative factors. The synergistic effect of ooshakadi gana medicines enhances the kshara guna (alkaline property) effect of gomutra (cow urine) and yavakshara (an alkaline substance) because they both have similar properties.

Lekhana Basti is a hypertonic solution. When this hypertonic solution enters the large intestine, it creates an osmotic pressure gradient, causing the body fluids to flow from hypotonic to hypertonic solutions along with harmful substances like LDL cholesterol. The unwanted metabolites are dragged from inter-intracellular levels to the large intestine and then expelled from the body. Due to the rich vasculature of the rectum and the special Lekhana Basti yoga formulations, drugs are absorbed and pass through the rectal mucosa through the mechanism of selective permeability. The majority of the active ingredients in the formulation mentioned above are of an alkaline type. This restores the rectal mucosa's physiological pH, which promotes bacterial flora formation and activates the enzymes necessary for the appropriate cholesterol metabolism. Most of the formulation's constituents have been tested for their ability to alleviate hyperlipidemia.

Preclinical tests on rats showed that honey had anti-hyperlipidemic activity. [26] According to a study, type 2 diabetics who received honey had lessened insulin resistance [27] This is an essential finding as insulin resistance is one of the critical

components of Metabolic Syndrome. Reduced Triglycerides [28] or elevated high-density lipoprotein (HDL) cholesterol [29] were observed in rats fed honey. A study determined that Triphala (a mixture of *Emblica officinalis, Terminalia bellirica* and *Terminalia chebula*) had hypolipidaemic effects on total lipids and free fatty acids in experimentally produced hypercholesteremic rats [30].

It is speculated that the medications absorbed either enter the systemic circulation directly through the middle and inferior rectal veins from the lower rectal mucosa or reach the portal circulation through superior hemorrhoidal veins from the upper rectal mucosa. Once they enter the liver, these active ingredients stimulate the formation of bile salts, which regulate the emulsification of lipids and prevent fatty deposits in the liver and blood cells. As the active ingredients are alkaline, they scrape the lipids in blood vessels, lowering sandrata (blood density). Hence, avoiding atherosclerosis is a crucial risk factor for CHD.

The large intestine contains the most significant number of nerve plexuses and lumbo sacral plexus spreading all over the body. The entity of the tasks carried out by the two previously mentioned plexuses is thought to represent the Vata dosha (one of the three bodily humours representing air). Employing the Basti treatment, Vata is channelized, stimulating some endocrine glands to release their enzymes, such as pancreatic lipase and acetyl-a coenzyme, which are responsible for fat metabolism. Basti dravyas are absorbed into rasayani or sira (channels), often carrying Rakta and Rasa. Through these sira and rasayani, the enhanced meda dhatu also travels to deha sanchari (the entire body). It appears as more lipids flowing via Rasa and Rakta. As a result, the medications given in the form of Basti have an impact even on Rakta dhatu, which has higher levels of circulating lipids.

Some of the researches on Lekhana Basti

1] Gupta Arun *et al.* conducted a clinical trial entitled "Lekhana basti: An Alternative for Bariatric Surgery". They concluded that Lekhana Basti produced significant results in both subjective and objective parameters of obesity [31].

2] Another clinical trial entitled "The effect of Lekhana Basti in the management of Sthoulya" was conducted by Nisargi Ramachandra *et al.,* and they concluded that Lekhana Basti has a significant role in reducing BMI, VLDL cholesterol and Triglyceride level [32].

3] Sreelakshmi Chaganti *et al.* conducted a single-blinded randomized controlled study entitled "Evaluation of efficacy of Ooshakadi Lekhana Basti in the hyperlipidemia-A single-blinded randomized controlled study" They found that Ooshakadi Lekhana Basti is effective in hyperlipidemia and more efficacious in the group of non-obese hyperlipidemic patients [33].

Remarkable points of the clinical trial

a) Subjects showed remarkable improvement in waist circumference but significantly less weight reduction. Lekhana Basti probably significantly affects Vayu mahabhoot (air element) and Akash mahabhoot (space element).

b) Females with irregular periods had periods on time with Lekhana Basti treatment. As we all know, Basti balances the functions of Vata, and the obstruction in the flow of periods is due to the malfunctioning of Vata.

c) Some patients suffer from abdominal cramps after administering Lekhana Basti dravya, so deepan (igniting digestive fire) and paachan (enhancing digestion) can subside this problem.

Limitations and suggestions

The study design included 15 days for one sitting. There was a non-significant result in the criteria of Triglycerides and HDL. Swapnil *et al.* conducted a clinical trial entitled 'Assessment of Lekhana Basti in the management of hyperlipidemia' with similar results. They concluded that the metabolism of lipids is complex and requires correction from the Jatharagni level to the Dhatvagni level. Hence, the time for which the Lekhana basti was given was probably shorter duration, so it did not provide effective results. [34] The study can be done for a longer duration for better results.

CONCLUSION

Lekhana Basti is a suitable treatment option due to its properties of lekhana (scrapping lipid from tissue), rukshna (dry), and ushna (hot). Lekhana Basti is a significant samshodhana (eliminating morbid dosha out of the body) treatment that is essential for eliminating the body's harmful disease-causing metabolites and helps alleviate the symptoms of Metabolic Syndrome.

Hence, it can be concluded that Lekhana Basti is an effective treatment modality for Metabolic Syndrome.

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