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Research Article

COMPARATIVE EVALUATION OF *VIRECHANA KARMA* AND *LEKHANA BASTI* IN THE MANAGEMENT OF METABOLIC SYNDROME

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ABSTRACT

Metabolic Syndrome is a complex metabolic condition which is a rising therapeutic problem in modern society. Additionally, it has been linked to the emergence of CVD, Type 2 DM and other grave health issues. It primarily develops as a result of a diet high in fat, a sedentary lifestyle, stress, insomnia, drinking too much alcohol, being overweight, and other factors. When three out of the five biochemical and physiological abnormalities such as visceral obesity, dyslipidemia, hypertension, increased blood sugar, insulin resistance, etc. are present in the body, it is considered clinically diagnosed. *Acharya Charaka* has mentioned a group of diseases namely *Santarpana Nimittaj Vikara* (diseases caused due to over eating) which can be symptomatically co-related with metabolic syndrome, especially *Medaavrit* (covered by fatty tissues) *Vata* (one of the three bodily humors representing air in the body). **Aims & Objectives:** Comparative evaluation of *Virechana Karma* (therapeutic purgation) and *Lekhana Basti* (a type of therapeutic enema) in the management of metabolic syndrome. **Material & Methods:** 43 patients were selected on the basis of classical symptomatology of metabolic syndrome from OPD and IPD of Dept. of *Panchakarma*, Hospital of Rishikul Campus and randomly divided into two groups - *Virechana* group and *Lekhana Basti* group on the basis of inclusion - exclusion criteria. There after the patients were subjected for detailed clinical history and physical examination. **Statistical analysis used:** Since objective criteria were selected so for intragroup comparison Paired- t- test was applied and for intergroup comparison Unpaired-t- test (t-test) was applied. **Conclusion:** *Virechana Karma* is better than *Lekhana Basti* in the management of metabolic syndrome.

INTRODUCTION

Metabolic syndrome is an umbrella term used to describe a variety of health conditions, including high blood pressure, dyslipidaemia, insulin resistance, obesity, and glucose intolerance, which all contribute to an individual's likelihood of developing cardiovascular diseases (CVDs) or type 2 diabetes.[1,2] People have come up with all sorts of different definitions for Metabolic Syndrome, but the one that's most popular is the one put forth by the National Cholesterol Education Program Adult Treatment Panel III (ATP III). It has specific criteria for what it is, which makes it easy to figure out who has it and how to classify them[3]. It is estimated that approximately 20% to 30% of middle-aged individuals suffer from this syndrome[4]. It is estimated that between 8 and 24% of men and between 7 and 46% of women experience the syndrome[5,6,7]. It looks like metabolic syndrome is becoming more common in developing countries and in Asia, according to some research done in this field [8]. In Ayurvedic Literature, Acharya Charaka has mentioned a group of diseases which arises due to over intake of heavy meals and sedentary lifestyle collectively called as *Santarpana nimitaj Vikara* which can be symptomatically co-related with metabolic syndrome, especially *Medaavrit Vata* described in Charaka Samhita. In Modern medical science-moderate calorie restriction, fiber rich diet, increase in physical

activity and quitting addiction (smoking and alcohol) is followed as primary intervention in treating metabolic syndrome. Further symptomatic drug therapies are used to pacify different diseased conditions like antihypertensive drugs for hypertension, cholesterol reducing drugs, anti-diabetic drugs, liposuction for removing subcutaneous fats etc. On the other hand, Acharya Charaka and Shushruta described the treatment for *Santarpana Nimittaj Vikara* by *Samshodhana* (complete purification), medicines, dietary changes and exercise. Ayurvedic treatment also includes *Nidan Parivarjan* (removal of cause) and use of drugs for the treatment of *Santarpana Nimitaj Vikara* like modern medicines but the main difference is in the concept of removal of *Doshas* (the three bodily humors) and cleansing congested *Srotas* (channels) which helps in removing harmful chemical metabolites from the body and therefore not only preventing but also uprooting the cause that may otherwise further manifest into more complicated conditions and also preventing the recurrence of the current ailment. Understanding the importance of cleansing process in the treatment of metabolic syndrome we have chosen two important *Samshodhana karmas* "*Virechana*" and "*Lekhana Basti*" described in the Ayurvedic text for the treatment.

AIMS AND OBJECTIVES

Comparitive evaluation of *Virechana Karma* and *Lekhana Basti* in the management of metabolic syndrome.

MATERIAL AND METHODS

Selection of Patients: The study comprises 43 patients of metabolic syndrome.

Ethical Clearance: The research has been ethically approved by Uttarakhand Ayurved University and also enrolled in CTRI with CTRI number CTRI/2018/05/014339. Written consent was taken from all the subjects before the trial and study was in accordance with ICH GCP guidelines.

Type of Study: Randomized open clinical trial

Duration of Study: 60 days

Assessment: Done at interval of 15 days

Inclusion Criteria (NCEP ATP III)

1. **Age**: 20- 60 years
2. **Fasting glucose:** $\geq$ 100mg/dl (not receiving drug therapy for hyperglycemia).
3. **Blood pressure:** $\geq$ 130/85mmHg (not receiving drug therapy for hypertension).
4. **HDL-C**: $\geq$ 40mg/dl in men or < 50mg/dl in women (not receiving drug therapy for reduced HDL-C)
5. **Waist circumference:** $\geq$102cm (40 inches) in men or 88cm (35 inches) in women, if ASIAN $\geq$ 90cm (35 inches) in men or $\geq$ 80cm (32 inches) in women.
6. **Triglycerides:** $\geq$150mg/dl

* (any three from serial no. 2 to 6)

7. Patient fit for *Virechana* procedure [9].
8. Patient fit for *Basti* (therapeutic enema) procedure [10].

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 ano-rectal ailments.

From patients, written informed consents were taken before entering into study. The importance of them for adherence to the treatment, *Pathya-Apathya* (do's and don'ts) associated with the disease, schedule for follow up, dates for visits to hospital was issued.

Laboratory Investigations

1. Routine haematological, urine examination
2. Blood sugar (Fasting)
3. Lipid Profile
4. Renal Function Test, X- ray Chest, E.C.G., Liver Function Test, (If required)

Withdrawal criteria

1. Personal matters
2. Inter-current illness
3. Aggravation of complaints
4. Patient develops any serious adverse effect

Study Methodology

Groups of Treatment

The patients were randomly categorized into the following two groups.

Virechana group (Group A)

In this group, a total of 22 patients were registered, out of whom 20 completed and 2 discontinued the course of therapy.

Lekhana Basti group (Group B)

In this group, a total of 21 patients were registered, out of whom 13 completed and 8 discontinued the course of treatment.

Methodology for *Virechana Karma*

Procedure of *Virechana*: All the 22 patients were treated with *Virechana Karma* in 2 consecutive sitting with a gap of 15 days in between.

Purva karma (before the main procedure)

***Deepan-Pachana* (process to ignite digestive fire and stimulate digestion):** It was carried out with *Churna* (medicine in the form of powder) or *Vati* (tablet) depending upon the *Agni* (digestive fire), *Koshtha* (nature of bowel habit) and *Prakriti* (basic nature) of the patient.

***Snehpana*:** (internal oleation) *Sneha* (oil) was also given according to *Koshtha* and *Agni* of patient till appearance of *Samyaka Snigdha Lakshana* (symptoms

of proper oleation) for *Abhyantar Snehapaan* (internal oleation) in an increasing dose of 30-50ml/day for a period of 3-7 days.

Bahya Sneha **(external oleation)***:* Then *Sarvanga Snehana* (full body oleation) and *Swedana* (sudation therapy) was done for three days after *Snehpana*.

Pradhana karma **(main procedure):** *Virechana Dravya* (medicines used for purgation) according to *Koshtha* was given in empty stomach at 9:30 a.m. - 10:30 a.m. Process was continued till *Samyaka Shuddhi Lakshana* (till attainment of complete purgation) was obtained.

Paschata karma **(after the main procedure)**

Depending upon *Shuddhi, Samsarjana Krama* (dietary regimen followed after the procedure) was done for 3-7 days in which *Peya* (cooked rice water), *Vilepi* (rice water thick in consistency), *Yusha* (soup), *Ghrita Yukta Krushara* (a dish with rice and lentils and clarified butter)), etc., were given after *Virechana*.

Follow up: After the completion of the therapy, patient was advised to visit O.P.D. at interval of 30 days for 60 days.

Methodology for *Lekhana Basti*

All 21 patients were administrated with *Lekhana Basti*.

Poorva Karma: *Sthanik Abhyanga* (local oleation) and *Nadi Sweda* (a type of sudation) of *Kati Pradesh* (low back region)*.*

Pradhan Karma

The complete *Lekhana Basti* procedure included *Lekhan Basti* in the morning for 15 days along with *Matra Basti* (therapeutic enema using small quantity of oil) in the evening. Administration of *Sukhoshna* (soothing temperature) *Basti Dravya* (materials used in enema) in *Vama Paarshwa* (left lateral position) was done. Then after giving 15 days interval same procedure was repeated. Then result was observed after 15 days.

Paschata Karma: Patient was advised to follow diet regimen in *Basti Parihara Kala* (recovery period)*.*

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

Objective parameters (Following NCEP ATP III criteria)

Pre-treatment and clinical observational data were collected from the registered patients. They were then evaluated for the chief objective parameters mentioned in table 1. Assessment was done before the initiation of trial and regular interval of the procedure for 60 days. Follow up was done after completion of the trial for one month to look for any recurrence.

Table 1: Assessment of the Patient on following parameters

Parameter	Before Treatment	1st Follow up	2nd Follow up	After Treatment
Weight				
Waist Circumference				
Blood Sugar (F)				
Blood Pressure				
Triglycerides				
HDL				
LDL				

To assess the effect of therapy objectively, all the signs and symptoms were observed on the basis of 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: For intra group comparison of objective parameters Paired- t test was applied and for inter group comparison Unpaired - t test (t- test) was applied. The obtained results were interpreted as:

Table3: 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

No. of groups - 2

Group A- *Virechana Karma* group

Group B- *Lekhana Basti* group

Table 4: Demographic data collected from the patients

Group	Total registered patients	LAMA cases	Patients for study
Group A	22	2	20
Group B	21	8	13
Total	43	10	33

Table 5: Category with maximum percentage in particular criteria

Criteria	Category	Maximum Percentage
Age	41-50 years	37.20%
Gender	Female	89.39%
Habitat	Urban	90.69%
Marital status	Married	90.69%
Socioeconomic Status	Middle class	58.13%
Occupation	Housewife	60.46%
Addiction	Non addicts	74.41%
Diet	Mixed	53.48%
Koshtha	*Madhyam*	76.74%
Nature of work	Physical	62.79%
Exercise	No exercise	60.46%
Sleep	Sound sleep	74.41%
Prakriti	KP	69.76%
Gynecological History	Regular, Menopausal	42.85%

Post Treatment Observations

Table 6: Statistical Analysis of Comparative evaluation of *Virechana karma* and *Lekhana basti* in the objective parameters of Metabolic Syndrome

| Parameters	Mean		SD		t-Value	P-Value	Result
	Gr. A	Gr. B	Gr. A	Gr. B			
Weight	5.700	3.508	1.261	2.212	3.634	<0.001	HS
Waist Circumference	4.825	5.923	3.246	1.891	-1.101	>0.05	NS
Systolic BP	4.700	5.462	5.555	5.607	-0.383	>0.05	NS
Diastolic BP	3.300	5.231	6.845	4.285	-0.905	>0.05	NS
Blood Sugar Fasting	3.018	16.269	13.750	14.089	-2.679	<0.05	S
Triglyceride	30.898	12.378	29.992	57.143	1.220	>0.05	NS
HDL	-4.871	-2.292	4.726	7.393	-1.226	>0.05	NS
LDL	24.886	27.173	22.434	36.753	-0.223	>0.05	NS
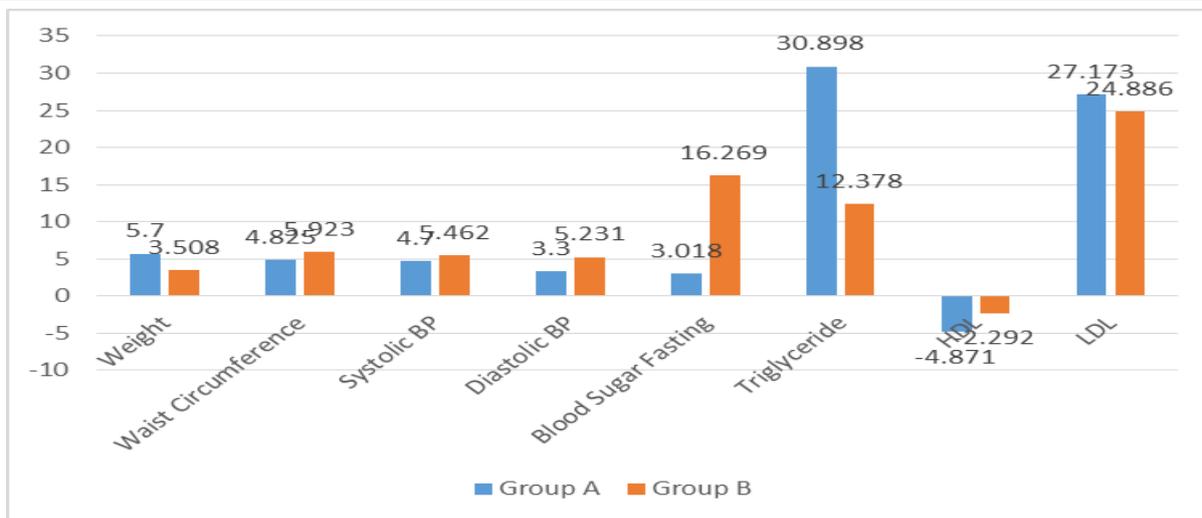
Figure 1: Comparative Evaluation of Group A and Group B on objective parameters

Table 7: Overall result of improvement

Overall improvement	Group A		Group B	
	Frequency	Percentage	Frequency	Percentage
Complete remission	0	0.00	0	0.00
Marked improvement	0	0.00	0	0.00
Moderate improvement	5	25%	3	23.08%
Mild improvement	12	60%	7	53.84%
No improvement	3	15%	3	23.08%
Total	20	100%	13	100%

DISCUSSION

As we have taken comparative evaluation of *Virechana karma* and *Lekhana basti* in the management of metabolic syndrome, it is mandatory to illustrate mode of action of *Virechana Karma*, mode of action of *Lekhana basti* and probable process of development of metabolic syndrome and effect of therapy on it.

As we know, metabolic syndrome is a lifestyle disorder and subjects from different parts of world have different lifestyle. So, we must evaluate the process of development of disease in the area of study i.e., Haridwar (Uttarakhand).

We can summarize illustration in following parts-

1. Analytical discussion of disease

2. Analysis of the mode of the action of *Virechana karma*

3. Analysis of the mode of the action of *Lekhana basti*

4. Analysis of observation and results

Analytical Discussion of Disease

Speaking in terms of Ayurveda metabolic syndrome results from excessive nutrient intake as a result of poor tissue metabolism. Ayurveda has a very vivid concept of obesity and lipid disorders, as it relates to *Medoroga* (dyslipidaemia) and *Prameha* (diabetes). Ayurveda explains how to maintain a healthy quantity and quality of fatty tissues in the body in detail while discussing *Medadhatu* (lipid tissue) in the context of the *Medoroga* or *Sthaulya Roga* (obesity). [11] It affects and changes the integrity of fatty tissues including cholesterol, when *Meda Dhatu* interacts with *Ama* (unripe by product of impaired metabolism) in its preformed state. The primary cause of *Medo Roga* is an interaction between *Ama* and fatty tissues known as *Sama Meda Dhatu* (fatty tissue with *Ama*), and the *Yakrita* (liver) is in charge of the qualitative derangement of the lipids and cholesterol. When this type of *Ama* circulates throughout the body, it may clog micro channels, trigger immune responses and activate a generalized chain of inflammatory processes. Such a group of *Ama* could interact with *Meda Dhatu* and cause metabolic problems. Additionally, this sort of *Meda* is checking *Vata* functions at the tissue level, which may eventually result in insulin resistance and type 2 Diabetes. [12] The *Baddha Meda* (depository fats) is deposited in the subcutaneous region or left unutilized, which causes the waist circumference to increase and finally results in central obesity, which is the primary contributing reason for the assessment and diagnosis of metabolic syndrome. The entire process is explained in Ayurveda under *Santarpana Janya Vikara*, with *Vata Dosha* playing a prominent role which in turn causes *Vishamagni* (type of digestive fire that is erratic) and increased hunger. [13]
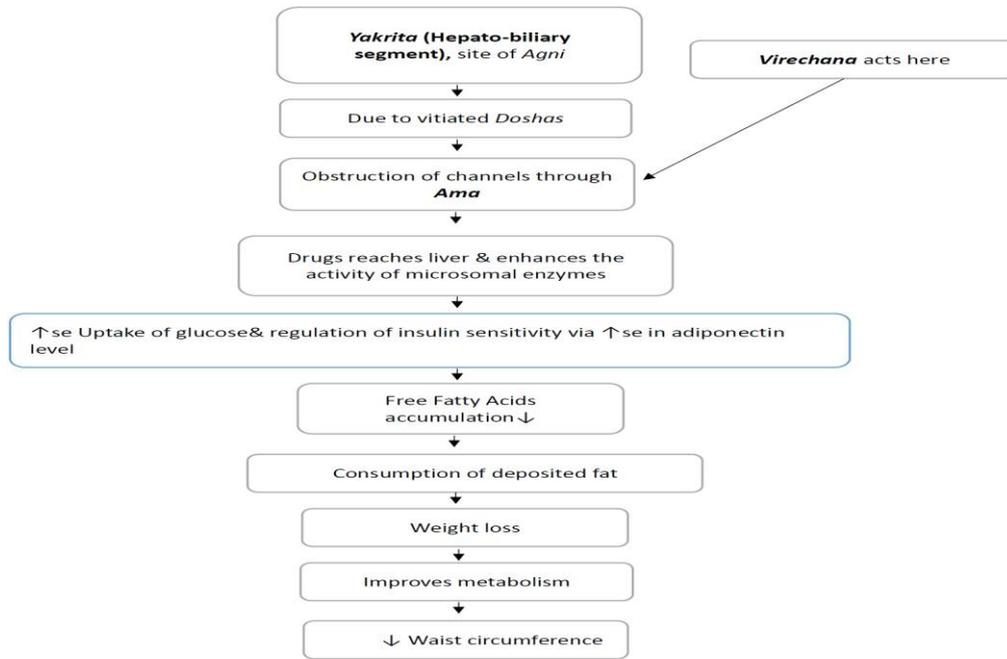
Analysis of the mode of action of *Virechana Karma*

Figure 3: Showing the mode of action of *Virechana Karma* in Metabolic Syndrome [14]

Analysis of the mode of action of *Lekhana Basti*

The use of numerous medication combinations accounts for the multifaceted effects of *Lekhana Basti* [15]. After entering *Pakvashaya* (large intestine) or *Guda* (anus)*, Lekhana Basti* operates on the entire body. *Guda* is described as *Sharira Mula* (vital part of the body) and has *Shira* (blood vessels) and *Dhamani* (artery) that spread all over the body. *Basti Dravya* restore *Apana Vata* (the type of *Vata* which controls all the downward movements of the body), maintaining its proper functioning and also improves the function of *Purisha* (stool)*.* One of the functions of *Purisha* is '*Anila Anala Dharana'* (maintain balance between the air and fire element in the body), thus *Basti* leads to correction of *Agni Dushti* (improper functioning of digestive fire). Since *Agni Dushti* is the primary cause of metabolic syndrome, *Lekhana Basti* aids in reducing its symptoms by correcting *Agni Dushti*.

As per modern appraise, the intestines are highly innervated. The *Basti* drugs stimulate the specific receptors present in the intestines which activate the autonomic nervous system and send signals to the brain. This helps in removal of morbid *Doshas* and excessive fat.

Analysis of observation and result

Analysis of Pre-treatment observations

Age of Onset: The peak prevalence was observed in the subjects aged 41-50 which was 37.22%. Santos AC et al (2008), Lee WY et al (2005) showed that participants aged more than 40 years old exhibited higher prevalence of metabolic syndrome and hypertriglyceridemia-waist than younger participants. Gomez-Huelgas et al. also stated that hypertriglyceridemia-waist increased with age.

Sex: 81.40% subjects were females. Lydia U. Kaduka et al (2008), Miccoli R et al (2005), Son lN et al (2005), Rahim MA et al (2007) Bentley-Lewis R et al found in their study that metabolic syndrome is more prevalent in females. Pregnancy, lactation, gestational diabetes mellitus, pre-eclampsia, hormonal contraceptives, menopause and polycystic ovary syndrome are several factors unique to women that can impact the prevalence and characteristics of metabolic syndrome in women.

Habitat: 90.70% lived in urban habitat. The possible reason: could be the location of hospital in the urban area of Haridwar, so maximum patients came from the peripheral areas. The secondary reason could be faulty dietary habits and lifestyle of people residing in urban areas which leads to metabolic syndrome.

Occupation: 60.46% were housewives. As metabolic syndrome is a disease of sedentary lifestyle and generally housewives of modernized era are more dependent on household helpers. Irregular dietary habits, habit of day-sleep etc. which causes *Ama* formation. Moreover, due to responsibilities housewives generally don't take care of their health.

Socio- Economic Status: 58.13% of the patients were from middle socioeconomic status. Since, metabolic syndrome is a disease of developed and developing countries it is been more found in middle socioeconomic status in Haridwar.

Dietary Habits: 53.48% patients were taking mixed diet, especially sweets and bakery products which are directly responsible for increasing BP, cholesterol, weight and hence contributing to metabolic syndrome.

***Koshtha* (Nature of bowel habits):** 76.75% were *Madhyama Koshthi* (normal bowel habits). This shows that metabolic syndrome does not directly links with the *Koshtha* of the patients.

Exercise Habits: 60.46% were doing no exercise, as metabolic syndrome is a disease of sedentary lifestyle and lack of physical activities.

Addiction: 74.42% were non-addicts. This reveals that addiction does not play much role in developing metabolic syndrome. Moreover, as maximum subjects were females, so the percentage of non-addicts is greater than the ones with addiction.

Sleep Pattern: 74.42% patients had sound sleep. As in Metabolic Syndrome there is aggravation of mainly *Kapha Dosha* and *Meda Dhatu Dushti*, hence people have sound sleep.

***Prakriti*:** 69.76% were of *KP Prakriti*. Metabolic Syndrome is a disease due to aggravation of *Kapha Dosha* initially and later on *Pitta* and *Vata Dosha* involvement. That's why *Kapha- Pitta Prakriti* patients were observed.

Gynaecological History: 42.85% had regular menstrual cycle and 42.85% patients were in the menopausal stage. It seems that in the menopausal stage there are hormonal changes which are responsible for increase in FFA resulting into dyslipidemia, which in turn contributes to metabolic syndrome.

Analysis of post treatment observations

Weight

There is 7.05% reduction in weight in Group A and 4.06% reduction in Group B. Greater reduction in *Virechana* group may be due to the fact that the *Virechana Dravya* are basically *Prithvi* (earth element) and *Jal Mahabhoot Pradhan* (mainly water element), it would probably extract out metabolites that are *Prithvi* and *Jal Mahabhoot Pradhan*, being *Samana Guna Dharmi* (having similar properties), thus reducing weight. On the other hand, *Basti Chikitsa* (treatment) is basically for *Vayu*, then other *Dosha.*

Waist Circumference

There is 35.44% reduction in waist circumference in Group A and 33.65% reduction in Group B.

Blood Sugar Fasting

There is 27.46% relief in blood sugar fasting in Group A and 77.37% relief in Group B. *Lekhana Basti* group was more effective, the contents of *Lekhana Basti* are *Katu* (pungent)*, Tikta* (bitter), and *Kashaya* (astringent) *Rasa Pradhan*. Also, *Ushna* (hot)*, Tikshna* (sharp)*, Laghu* (light)*, Rooksha* (dry) *Guna* (quality) are the inherent qualities with *Ushna Virya* (hot potency) and *Katu Vipaka* (final outcome after digestion). All these help in pacifying *Kapha Dosha*. Since Blood sugar is mainly *Kapha* (body humor

representing water in the body) *Pradhan Vyadhi* according to Ayurveda, so helps in maintaining blood sugar. On the other hand, *Virechana* is mainly for pacifying *Pitta* (one of the three bodily humors representing fire in the body)

Systolic BP

There is 65.85% relief in Group A in systolic BP and 82.25% relief in Group B.

Diastolic BP

There is 79.03% relief in Group A and 87.50% relief in Group B.

Triglycerides

There is 100% relief in Group A and -7.43% in Group B. Swapnil et al conducted a clinical trial which had similar results. They concluded that the metabolism of lipids is complex and requires correction from *Jatharagni* (main digestive fire) level to *Dhatvagni* (tissue metabolism), hence the time for which the *Lekhana Basti* was given was probably shorter duration so did not give effective results.

HDL

There is 40.27% relief in Group A and 27.71% relief in Group B.

LDL

There is 87.67% relief in Group A and 27.71% relief in Group B.

CONCLUSION

- In all the parameters both the treatment modalities i.e., *Virechana karma* and *Lekhana Basti* are equally effective except:
- Weight: *Virechana Karma* had better result than *Lekhana Basti.*
- Fasting blood sugar: *Lekhana Basti* had better result than *Virechana Karma*
- As far as overall improvement of patients is concerned:

***Virechana Karma* is better than *Lekhana Basti* in the treatment of Metabolic Syndrome**

Suggestions for future studies

1) To demonstrate the assessment factors of metabolic syndrome in large sample size.

2) *Lekhana Basti* should be given for a longer period of time for better results.

3) Better identification of high-risk patients with Metabolic Syndrome under different sets of *Prakriti.*

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