A clinical study on *Virechana Karma* (therapeutic purgation) over the gut flora with special reference to obesity

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Abstract

Background: Altered gut flora is associated with the pathogenesis of both intestinal and extra-intestinal disorders. Actiology of obesity is associated with mechanisms such as short chain fatty acid production, stimulation of hormones, chronic low-grade inflammation, lipoprotein and bile acid metabolism and increased endocannabinoid. Receptor system tone have been suggested to explain the role of gut microbiota of obesity. The *Panchakarma* (Ayurvedic purification methods) claims the management of metabolic disorders hence this work provides the target specific evidence for the clinical studies. The proposed project is aimed to explore the particular molecular mechanism and, to make this therapy more evidence based. Hence, it was hypothesized that *Panchakarma*-based intervention such as *Virechana Karma* (therapeutic purgation) may influence microbiota and help in the management of the obesity. **Materials and Methods:** The study was conducted to explore the effect of *Virechana Karma* over the gut flora; therefore, total of 19 patients with *Madhyama Koshtha* diagnosed with obesity were included and received the intervention. Before and after *Virechana*, a stool sample was collected and processed for the enterobacterial repetitive intergenic consensus -polymerase chain reaction to find the changes over the facultative aerobic bacteria. **Results:** It was found that *Virechana* is effective in the management of the obesity. **Conclusion:** *Virechana* is effective in the management of the obesity due to reduction in the signs and symptoms of obesity. **Conclusion:** *Virechana* is effective in the management of the obesity due to reduction in the signs and symptoms of obesity.

Keywords: Aerobic bacteria, ERIC-polymerase chain reaction, gut flora, obesity, Panchakarma, Virechana

Introduction

Obesity is a leading but preventable cause of death worldwide, with increasing prevalence in adults and children, which makes it one of the most serious public health problems of the 21st century. Of late, it has been reported that it has a positive correlation with insulin resistance and is a strong risk factor for cardiovascular diseases and a strong predictor of future diabetes mellitus. It is estimated that 20%–25% of South Asians have developed insulin resistance and many more may be prone to it.^[1-4]

Dysbiosis of the gut microbiota is associated with the pathogenesis of both intestinal and extraintestinal disorders. Intestinal disorders include inflammatory bowel disease, irritable bowel syndrome and coeliac disease, while extraintestinal disorders include allergy, asthma, metabolic syndrome, cardiovascular disease and obesity^[5] Currently,

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DOI: 10.4103/ayu.AYU_302_19

there is no definite medical treatment and to manage the obesity properly that too without any side effect.^[6]

Sthaulya (obesity) is listed as one among the Ashta Nindita Purusha; (physical unfit patients usually with genetic predisposition).^[7] The cardinal symptoms of Sthaulya are Medomamsa Ativriddhi (excess of fat accumulation), Chalasphika, Chalaudara, Chalastana (flabbiness at the buttocks, abdomen, and chest), Ayathaopachaya (excessive and disproportionate accumulation of fat) and Anutsaha (fatigue).^[8]

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How to cite this article: Chaturvedi A, Nath G, Yadav VB, Antiwal M, Shakya N, Swathi C, *et al.* A clinical study on *Virechana Karma* (therapeutic purgation) over obesity gut flora. AYU 2019;40:179-84.

Revised: 09-Mar-2020

Published: 08-Aug-2020

Submitted: 11-Nov-2019 Accepted: 11-Apr-2020

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Besides these symptoms, *Ashtadosha* (eight complications) of *Sthaulya* has also been mentioned in Ayurveda texts.^[9]

Panchakarma is a specially designed set of five procedures of internal purification of the body through the nearest possible route. Such purification allows the biological system to return to homeostasis and to rejuvenate rapidly and also facilities the desired pharmaco-therapeutic effects of medicine. The elimination of waste products is known as Shodhana (purification). These are performed in three phases: Preparatory, main procedure and post-operative phase. Though many clinical studies carried out in Ayurvedic institutions have proved the clinical efficacy of these procedures in metabolic disorders like obesity, diabetes mellitus, but it has not yet received much attention in regards to its mechanism and modern investigations possibly due to the conceptual compatibility difficulties. In Ayurvedic literature, it has been clearly mentioned that these procedures can act as a curative, preventive and health promotive measure. Obesity is a Santarpanajanya Vikara, i.e., occurring due to over nourishment,^[10] where in there is a role of Srotorodha (obstruction in the systemic channels), improper Agni, and disarrangement of Tridosha.[11] Virechana Karma (therapeutic purgation) is one of the treatment modalities for treating Santarpanajanya Vikaras.[12] Virechana Karma clears the Srotoavarodha (obstruction), normalizes the Agni and brings balanced state of Tridosha.[13,14]

Many studies are looking at therapy that might improve some of the adverse effects of obesity.^[15] The *Panchakarma* is indicated in the management of metabolic disorders; hence, this study may provide target specific evidence for the management of the obesity. The proposed project aimed to explore the molecular mechanism of *Virechana* so that to generate evidence for its action. Hence, it was hypothesized that *Panchakarma*-based intervention such as *Virechana Karma* may correct the altered gut microbiota and help in the management of obesity. Thus considering the above facts, this study was executed.

Materials and Methods

Patients diagnosed as a case of obesity as per diagnostic and inclusion criteria, irrespective of age, sex and religion were selected for the study, from the *Panchakarma* OPD & IPD of hospital, Banaras Hindu University, Varanasi, Uttar Pradesh, after approval from Institutional Ethics Committee (vide Dean/2017/EC/202 dated October 24, 2017) which was further registered with CTRI with CTRI/2018/07/014790. Consent was taken from each patient who was registered for the study.

Source of drug

 Drugs used for present clinical trial such as Udvartana Churna (powder for dry massage) were prepared from raw drugs such as Kulatha (Vigna unguiculata Linn.), Mudga (Vigna radiata (L.) R. Wilczek), Triphala (fine powder of Terminalia chebula Retz., Terminalia bellirica (Gaertn.) Roxb. and Emblica officinalis Gaertn. Sarshapa (Brassica juncea L. Czern. et Cosson), Methika (Trigonella foenum greacum Linn) and Yava (Hordeum vulgare Linn.) Trikatu *Churna* (powder of *Zingiber officinale* Rosc, *Piper nigrum* Linn. and *Piper longum* Linn); *Murchita Taila* (processed oil) and *Triphala Kwatha Churna* (coarse powder for decoction) were procured from pharmacy of the institute. *Trivritta Lehya* (compound of *Operculina turpethum* Linn.) was purchased from Nagarjuna Pharmacy, Kerala.

Methodology

Standardization of trial drug

Physicochemical characterization; determination of total ash, acid-insoluble ash and water-soluble ash; loss on drying at 110°C; water-soluble extractive test and alcohol-soluble extractive tests of the trial drugs were done as per the standards of Ayurvedic Pharmacopoeia of India.^[16] Disintegration time of the tablets was assessed as per the Indian Pharmacopoeia.^[17] High-performance thin-layer chromatography studies of all preparations such as *Trikatu Churna, Udvartana Churna, Murchita Taila* and *Trivruta Avaleha* were done as per the standard procedure and were found to be suitable and authentic vide analysis report 288/13073007-11.

Diagnostic criteria

- Obesity^[18] defined as waist circumference ≥90 cm for men and ≥80 cm for women or obesity range from Class I and II, i.e., body mass index (BMI) from 30 to 39.9 kg/m²
- 2. Triglycerides ≥150 mg/dL (or receiving drug therapy for hypertriglyceridemia)
- 3. High-density lipoprotein cholesterol (HDL-C) <40 mg/dL in men or <50 mg/dL in women (or receiving drug therapy for reducing HDL-C).

Inclusion criteria

- Diagnosed patients of obesity who are eligible for Virechana Karma^[18] and of Madhyama Koshtha
- 2. Patients belonging to the age group of 20–60 years and of either of sex.

Exclusion criteria

• Patients suffering from type 1 diabetes, gestational diabetes, uncontrolled diabetes mellitus (<200mg/dl), uncontrolled hypertension (<150/110 mm Hg), cardiovascular diseases and other chronic diseases or autoimmune diseases and who are dependent on steroids were excluded.

Assessment criteria

Clinical study

Patients were evaluated for severity of illness during and after the intervention based on parameters such as:

- 1. BMI (kg/m^2)
- 2. Waist circumference, hip circumference and waist-hip ratio
- 3. Reports for triglycerides and fasting blood sugar were done before treatment and after the treatment.

Microbiological study

After *Virechana*, stool samples were collected and isolation was done on MacConkey agar and then, the samples were subjected to enterobacterial repetitive intergenic consensus (ERIC)-polymerase chain reaction (PCR) which was done to rule out the variation in bacterial flora.

Plan of study

Purvakarma (preoperative)^[18]

- *Deepana Pachana* (drugs to improve appetite and digestion) was performed by the administration of *Trikatu* powder 3 g thrice daily before food with lukewarm water till the symptoms of appropriate *Agni Deepana* were attained
- Rukshana (improve appetite and digestion by drying therapy) with Sarvanga Udvartana (powder massage on whole body) was done with Churna which was prepared from Kulatha (Vigna unguiculata Linn.), Mudga (Vigna radiata (L.) R. Wilczek), Triphala (fine powder of Terminalia chebula Retz., Terminalia bellirica (Gaertn.) Roxb. and Emblica officinalis Gaertn, Sarshapa (Brassica juncea L. Czern. et Cosson), Methika (Trigonella foenum greacum Linn) and Yava (Hordeum vulgare Linn.) followed by hot water bath, which was done for 3 days
- Thereafter, *Snehapana* in *Arohana Krama* (internal oleation with increasing dose) with *Moorchita Tila Taila* (processed sesame oil) was done till proper oleation features were achieved
- During the gap of three days and day of *Virechana*, *Sarvanga Abhyanga* (oil massage) with *Moorchita Taila* was done followed by hot water bath.

Pradhana Karma (operative)

• *Virechana Karma* was performed by the administration of *Trivritta Avaleha* approximately 70 g along with 100 ml of *Triphala* decoction on the 4th day after performing of *Abhyanga* and *Svedana* on empty stomach.

Paschat Karma (postoperative)

 Samsarjana Krama (post-Virechana dietary regimen) was advised for 3–7 days depending on the Shuddhi Lakshanas (purification signs).

Statistical analysis

Statistical Package for the social science (SPSS) version 20 of IBM India Limited, Bengaluru, India was used for the data analysis. Paired *t*-test was used to analyze the significance of change in objective parameters normally distributed.

The obtained results were interpreted after 21 days of therapy along with one month of follow up as

- Not significant: P > 0.05
- Significant (S): P < 0.05 or P < 0.01
- Highly significant: $P \le 0.001$.

Observation

An accessible population of obesity of either sex in and around the district of the study who were representative of the target population participated in the study. A total of 32 patients were screened, 19 patients with *Madhyama Koshtha* diagnosed as case of obesity (as per the inclusion criteria) were included and received the intervention. However, one patient no follow-up was received without any reason and hence, the current study was analyzed on 18 patients.

In this study, 50% of the patients were from the age group of 31–40 years; 56.66% of the patients were female. About 77.8% of the patients were married. The 55.6% of the patients belonged to middle class and there were 66.7% of the patients who had a family history of obesity. Almost 83.3% of the patients were consuming mixed diet and the maximum of the patients had predominant *Kaphavata Prakriti* (66.66%).

After intervention, it was observed that the maximum of the patients, i.e., 77.8%, had *Kaphanta Virechana* (mucus in the stool passed in the end) with average 19 *Vegas* (bouts) and all of them attained *Laingiki Shuddhi* (signs of purification) like *Vatanulomana* (normal movement of *Vata), Srotovishuddhi* (channel purification), *Laghuta* (lightness of the body), *Vega Pravriti* (initiation of *Vega*) in proper time, and *Indriya Samprasada* (improved sensory and motor functions). Therefore, 55.55% were given *Samsarjana Krama* for 5 days.

Results

It was noticed that after *Virechana*, there was a feeling of lightness and enthusiasm along with reduction in the signs and symptoms of obesity, with an average reduction of 7–10 kilogram. After *Virechana*, there was a decrease in the body weight by 9.70%, BMI by 6.64%, waist circumference by 5.06%, hip circumference by 4.17%, waist–hip ratio by 1.40%, serum triglyceride was reduced by 22.45% and fasting blood sugar was reduced by 14.95%, which were statistically highly significant at P < 0.001 [Table 1]. After *Virechana*, the stool samples were collected and isolation was done, after which the samples were subjected to ERIC-PCR which has shown the variation in bacterial flora, as *Escherichia coli* colonization was reduced after *Virechana* and after follow–up, as shown in Figure 1.

Discussion

The current era has seen a man living a fast-paced life. One does not have time to follow a healthy lifestyle and dietetic rules. Human being has invented ways to save his energy but has continued to store energy more than what he needs. This is because we live in an environment where food is available at low cost and where physical activity has been engineered out of daily life; hence, central obesity is on a raise. To confirm this fact, a recent survey shows that there are >25% obese adults worldwide.^[19]

Among the total number of patients, 50% of the patients were observed in the age group of 31–40 years. This shows that obesity is more seen in middle-aged patients as they usually have a sedentary lifestyle. As a result of the positive energy balance, a gradual increase in weight occurs hence causing *Santarpana Janya Roga*. After *Snehapana*, all patients had *Adhastad Sneha Darshana* (steatorrhea), *Sneha Dvesha* (aversion to oil), *Vata Anulomana* (normal movement

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Variables	Interval	Mean	SD	SEM	t	df	Р
Weight (kg.)	BT - AV	7.11111	1.99673	0.47063	15.11	17	0.000
	BT - AS	7.55556	2.47867	0.58423	12.933	17	0.000
	AV - AS	0.44444	1.38148	0.32562	1.365	17	0.001
Hip circumference (cm)	BT - AV	4.16667	1.46528	0.34537	12.064	17	0.000
	BT - AS	5.33333	1.37199	0.32338	16.492	17	0.000
	AV - AS	1.16667	1.91741	0.45194	2.581	17	0.019
Waist circumference (cm)	BT - AV	4.72222	2.92666	0.68982	6.846	17	0.000
	BT - AS	6.16667	3.1483	0.74206	8.31	17	0.000
	AV - AS	1.44444	1.72259	0.40602	3.558	17	0.002
Waist-hip ratio (cm)	BT - AV	0.03278	0.07925	0.01868	1.755	17	0.037
	BT - AS	-0.02111	0.21166	0.04989	-0.423	17	0.022
	AV - AS	-0.05389	0.20434	0.04816	-1.119	17	0.048
Body mass index (kg/m ²)	BT - AV	2.82667	0.76471	0.18024	15.683	17	0.000
	BT - AS	3.28167	0.98892	0.23309	14.079	17	0.000
	AV - AS	0.455	0.55844	0.13162	3.457	17	0.003
Fasting blood sugar (mg/dl)	BT - AV	16.9411	10.74	2.53144	6.692	17	0.000
	BT - AV	13.5128	9.60094	2.26296	5.971	17	0.000
	AV - AS	-3.42833	6.0363	1.42277	-2.41	17	0.028
Serum triglyceride (mg/dl)	BT - AV	48.4333	47.8158	11.2703	4.297	17	0.000
	BT - AS	49.3833	53.7325	12.6649	3.899	17	0.001
	AV - AS	0.95	10.7603	2.53624	0.375	17	0.030

Table 1	Effect of	Virechana	Karma on	ohesitv	(objective	parameters)
		VIIGUIIAIIA		UNCOILV		

AS: After Samsarjana Krama, BT: Before therapy, AV: After Virechana SD: Standard deviation, SEM: Standard error of the mean, t: Student's t-test, df: The degrees of freedom

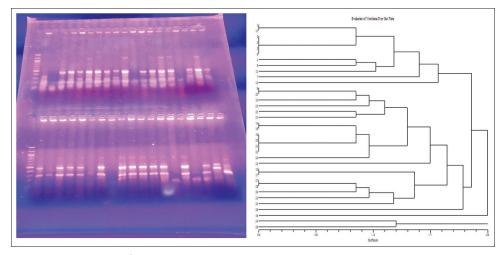


Figure 1: Enterobacterial Repetitive Intergenic Consensus-polymerase chain reaction and dandograph showing the changes over the obese gut flora before and after Virechana

of flatus & bowel) and Klama (fatigue). Adhastad Sneha Darshana indicates that the excessive fat is lost in the form of steatorrhea. Sneha Dvesha is because the large amount of fats that is given during Snehapana that initiates the inflammation of the gastrointestinal tract (GIT). Eighty percentage of the patient had Angamarda (bodyache), Angasadana (debility) and Snigdha Tvaka (oily skin). Most of these features were seen on the 3rd or 4th day of Snehapana. Since all the patients showed these symptoms, it can be said that the increasing dose pattern of Sneha administration (Avasthavishesha Aarohana) method of Snehapana is effective.

The reduction in the signs and symptoms of the obesity was significant with P < 0.001 as mentioned in Table 1. These results show that after Virechana, there was a feeling of lightness and enthusiasm along with a reduction in some of the complications in the patients of obesity. There was also reduction in the measurement of the body circumferences. Reduction of 7-10 kilogram and symptoms of obesity show target-specific therapy effect on insulin resistance which serves the primary outcome of the study. As per the current system of medicine, the first line of management recommends 5%-10% weight reduction for diabetes.^[5] Although there was a significant reduction in all the parameters after Virechana than before therapy, this shows the instant effect of *Virechana Karma* (bio purificatory action). After *Virechana*, the serum triglycerides and fasting blood glucose were also statistically highly significantly reduced. The study showed that there was a statistically highly significant changes in all the parameters of obesity.

Overall effect of the therapy

In the current study of eighteen patients, ten patients showed marked improvement and eight patients showed complete improvement over gut flora.

Probable mode of action

During the process of *Snehapana*, since the person was taking only *Taila* and a very small quantity of food, there is an acceleration of fat utilization for energy in the absence of carbohydrates. This absence of carbohydrate replenishment promotes mobilization of fatty acids from the adipose tissue. Thus, *Snehapana* has a weight reduction effect on the body. Prior to *Snehapana*, *Sarvanga Udvartana* was done which may cause the increase in the lymphatic drainage. It has been proved that lymphatic massage aids in water loss and thus ultimately weight loss.^[20]

Gastrium when filled with food inhibits signals to suppress the feeding center; a small quantity of fat is enough to cause this. Fat on entering the gastrium releases cholecystokinin which inhibits further eating. It also causes stimulation of the ventromedial nuclei of the hypothalamus, thus creating complete satiety. Next, when the chyme containing fat enters the duodenum, the activity of the pylorus pump is depressed and the pylorus sphincter is slightly closed. Thus, stomach emptying is slowed.

From the above factors, it is understand that during the process of *Snehapana*, there is a negative energy balance as it stimulates starvation.^[21] This shows the fact that *Sneha* administered for the purpose of *Shodhana* impairs the *Agni*,^[22] thus causing a negative energy balance.

Since there is a carbohydrate restriction in the diet, ketosis is induced. Hence, in the process of *Snehapana*, medically ketosis is induced. This can be explained as in the process of *Snehapana*, the source of energy is changed to proteins to begin with and then to fat, thus inducing ketosis. After digestion, the excessive fat is lost in the form of steatorrhea. For the purpose of *Shodhana Chikitsa*, the secretory action of the mucous membrane is exploited.

Here, *Moorchita Taila* was used for the purpose of *Snehapana*. The *Sneha* contains macromolecules of fat and micromolecules of the medicine. During the ingestion, the micromolecules of medicine are absorbed. Another reason is that, in a medicated *Taila*, the concentration of drugs is far more than the concentration of the drugs seen in other forms of medicines like *Kashaya* (decoction) or *Swarasa* (extracted juice of herb).^[23]

After the process of *Snehapana*, *Sarvanga Abhyanga* was done followed by *Swedana* in the form of hot water bath. Hot water bath causes hemoconcentration by the process of *Sarvanga Vashpa Svedana* and it also helps in burning calories.

Virechana is done on the 4th day. During the process of Shodhana,

the body fluids are influenced for therapeutic purposes; here, the body fluids are removed either through the upper or lower route. The GIT is lined by the mucous membrane which has a dual nature of absorption and secretion. The absorption nature is exploited for *Shamana Chikitsa* and the secretory nature is exploited in *Shodhana Chikitsa*. During the process of *Virechana*, cellular fluid is drained into the interstitial fluid, which is drained into the vascular compartment, from here it is drained into the GIT for elimination Thus, *Virechana* is targeted to create a biochemical alteration as it modulates the fluid compartments of the body.^[20-22]

During the process of *Virechana*, about 2 liter of the body fluid is drained out, which has dissolved biochemical in them. Thus, *Virechana* in the current study has shown its action in three ways. The drugs increase the secretion by irritating the mucous membrane of the GIT. Second, it prevents absorption of nutrients, and finally, it increases the gastro intestinal motility.

Thus, *Virechana* is targeted to create a biochemical alteration as it modulates the fluid compartments of the body. Further changes over the *E. coli* colonization were reduced after *Virechana* and after follow-up which shows the effect over the gut flora dysbiosis and further induces the stability of gut flora. studies have shown the changes in metabolites across many pathways such as phospholipid biosynthesis, choline metabolism, and lipoprotein metabolism. The observed plasma metabolomics alterations may reflect a *Panchakarma*-induced modulation of metabotypes. *Panchakarma* promotes statistically significant changes in plasma levels of phosphatidylcholines, sphingomyelins and others. Its influence over the immune responses are by regulating pro-inflammatory cytokines, immunoglobulins and functional properties of T-cells.^[24]

Conclusion

The result suggests that *Virechana Karma* and its preprocessing procedures both have fat metabolism correction activity against metabolism syndrome due to insulin resistance and reduces body weight, BMI, serum triglycerides and blood glucose level. This decreases fatty acid in the storage and adipose tissue that can also indirectly increase the insulin sensitivity in insulin receptor present at skeletal muscles. Furthermore, it can be concluded that *Virechana* is effective in the management of obesity due to a reduction in the *E. coli* colonization after *Virechana* by correcting gut flora dysbiosis.

Financial support and sponsorship Nil.

Conflicts of interest

There are no conflicts of interest.

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