Role of *virechana karma* in metabolic syndrome- Clinical trial

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Abstract

Metabolic Syndrome is a constellation of several factors like hyperglycemia, raised blood pressure, insulin resistance, dyslipidemia, and central obesity. Among these factors central obesity & insulin resistance are the dominant parameters of this collection. In today's era its prevalence is rising rapidly and it has a high socioeconomic burden. Being the major risk factor for Cardio Vascular Disease and Type 2 Diabetes Mellitus, it is the need of the hour to find a safe and cost effective remedy for Metabolic Syndrome. *Santarpana Nimittaj Vikara* in *Ayurvedic* Classics can be correlated to Metabolic Syndrome and *Virechana Karma* is an effective measure which helps in cleansing congested *Strotas* and removing vitiated *Dosha* hence pacifying the symptoms of Metabolic Syndrome. Patients of either sex in the age group of 20 to 60 years, fulfilling the study criteria were included in the study. Two sittings of *Virechana Karma* were administered with 15 day gap in between. Highly significant in all criteria except Blood sugar fasting. Conclusion: *Virechana Karma* is an ideal therapy for Metabolic Syndrome

Key words: *Metabolic Syndrome, Virechana Karma, Santarpana Nimittaj Vikara, Dosha, Strota, Type 2 Diabetes Mellitus*

Introduction

Metabolic Syndrome is a group of certain factors like hypertension, dyslipidemia, insulin resistance, obesity and glucose intolerance that increase a person's risk to develop cardiovascular disease (CVD) and type 2 diabetes (Miranda *et al.,* 2005). It has many synonyms ,the most common being Insulin Resistance 9Syndrome and Syndrome X. Although many definitions of Metabolic Syndrome have been proposed from time to time but the most widely accepted is that of the National Cholesterol Education Program Adult Treatment Panel ΙΠ (ATP ΙΠ) which has defined diagnostic criteria for Metabolic Syndrome , which is easily used for classifying patients (Grundy *et al.,* 2005). Estimates show that approximately 20-30% of the middle-aged population are affected by this syndrome (Meigs, 2002) .About 8 to 24% males (Gupta *et al.,* 2003; Ford *et al.,* 2002) and 7 to 46% females (Balkau *et al.,* 2003; Ramachandran *et al.,* 2003) are suffering from this syndrome. Some studies show an increasing prevalence of Metabolic Syndrome in developing countries and Asia (Meigs, 2000). It is as such not described in Ayurvedic classics, but we can symptomatically correlate it to *Santarpan Nimittaj* of treatment is treating the individual components of Metabolic Syndrome in order to enhance the overall condition of the patient. On the other hand, *Vikara* mentioned by Acharya Charaka (Shastri, 2009a). According to Modern Medicine, the basic principal treatment through *Ayurveda* includes removal of the root cause and cleansing congested *Strotas* (microchannel). *Virechana Karma* is an effective *Panchakarma* procedure that cleanses congested *Strotas* and removes vitiated *Dosha*, thus pacifying the symptoms of Metabolic Syndrome.

Aims and Objectives

To evaluate the efficacy of *Virechana Karma* in the Management of Metabolic Syndrome.

Material and Methods

Criteria for Selection of Patients

22 patients of Metabolic Syndrome were selected from the O.P.D. / I.P.D. Department of Panchakarma and Kayachikitsa, Rishikul Campus, Haridwar.

Ethical clearance- The research has been ethically approved by our University and also enrolled in CTRI with CTRI number CTRI/2018/05/014339. Written consent was taken from all the subjects

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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

A) 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 > 130/85mmHg (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. Patient fit for Virechana procedure (Shastri, 2009b).

(B) 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.
3. Aggravation of complaints
4. Patient develops any serious adverse effect (necessitating hospitalization)

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

Materials and Methods
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*:**
Deepan-Pachana: *It was carried out with Churna or Vati depending upon the Koshtha and prakriti of the patient.*

Snehpana: *Sneha* was also given according to *Koshtha* of patient till appearance of *Samyaka Snigdha Lakshana* for *Abhyantar Snehapaan* in increasing dose.
Bahya Sneha: Then *Sarvanga Snehana* and *Swedana* were done for three days after *Snehpana*.
***Pradhana Karma*:** *Virechana Dravya* according to *Koshtha* was given in empty stomach at 9:30 a.m. – 10:30 a.m. Process was continued till *Samyaka Shuddhi Lakshana* was obtained.
Paschata Karma: *Samsarjana Karma* was followed as per type of *Shuddhi.*
Follow Up: After the completion of the therapy, patient was advised to visit O.P.D. at interval of 30 days for 60 days.

Demographic data was collected from the registered patients along with baseline assessment according to the proforma. Periodic assessments of the patients were done at regular interval for 60 days. A follow-up assessment was done after one month to check the recurrence if any, after withdrawing the therapy.

Methods of data collection:
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 above parameters

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

Statistical analysis:
The information collected on the basis of above observations was subjected to statistical analysis using Graph Pad In stat, Software version 3.10 and SPSS software. For intra group comparison of objective parameters paired- t test was applied.

Thus the obtained results were interpreted as: P < 0.001 highly significant
P > 0.05 Not Significant
P < 0.01 & <0.05 significant

Table 2: Effect of Intervention on Objective Parameters

PARAMETER	Mean		%	SD	t-Value	P-Value	Result
	BT	AT					
Weight	80.800	75.100	7.05	1.261	20.219	<0.001	HS
Waist Circumference	107.2	102.37	35.44	3.246	6.649	<0.001	HS
Blood Sugar (F)	105.95	102.94	27.46	13.75	0.982	>0.05	NS
Systolic BP	129.80	125.10	65.85	5.55	3.784	0.001	HS
Diastolic BP	84.700	81.400	79.03	6.845	2.156	<0.05	S
Triglycerides	118.42	87.528	100	29.992	4.607	<0.001	HS
HDL	32.906	37.776	40.27	4.726	-4.609	<0.001	HS
LDL	117.25	92.370	87.67	22.434	4.961	<0.001	HS

Table 3: Estimation of overall Response of Treatment

Overall improvement	Frequency	Percentage
Cured	0	0.00
Marked improvement	0	0.00
Moderate improvement	5	25%
Mild improvement	12	60%
No improvement	3	15%
Total	20	100%

Results and Discussion

Total Registered patients- 22
Completed the treatment -20
            LAMA patients -2

1) Discussion of disease
The term Metabolic Syndrome as disease entity is not conceived in Ayurveda but the etiological factors for initiating the process of disease such as faulty dietary habits, life style errors, and defects in gene & variety of epigenetic factors have been clearly mentioned in the concept of health & disease. As per Ayurvedic parlance, Metabolic Syndrome is the outcome of over nutrition due to defective tissue metabolism. Obesity and lipid disorders have been vividly conceived in Ayurveda with context of *Medoroga & Prameha*. Ayurveda discusses *Medadhatu* (lipid tissue) in detail in the context of the *Medoroga* or *Sthaulya Roga* and clearly explains how to maintain healthy quantity and quality of fatty tissues in the body (Chaudhary,

2017b). When *Meda Dhatu* interacts with preformed form of *Ama*, it changes and alters the quality of fatty tissues including cholesterol. The interaction of *Ama* with fatty tissues is known as *Sama Meda dhatu*, which is the main cause of *Medo Roga*, and it is the liver (*Yakrita*) which is responsible for qualitative derangement of lipids and cholesterol. This form of *Ama*, when circulates all over the body may lead to blockade of micro channels and precipitate antigenic reactions & generic series of inflammatory events in the body. If such category of *Ama* interacts with *Meda Dhatu*, it may lead to metabolic disorders. Ayurveda also believes that this form of *Meda* is checking the function of *Vata* at tissue level that may lead to insulin-resistance & finally type 2 Diabetes mellitus (Tiwari, 2018).The *Baddha Meda* is deposited in subcutaneous region or unused and responsible for increased waist circumference, ultimately lead to central obesity, which is the key causative factor for

the assessment and diagnosis of Metabolic Syndrome. As in Ayurveda the whole process described under *Santarpana Janya Vyadhi* with major involvement of *Vata Dosha* which is cause of *Vishamagni* and increased hunger (Chaudhary, 2017b; Chaudhary, 2017c).
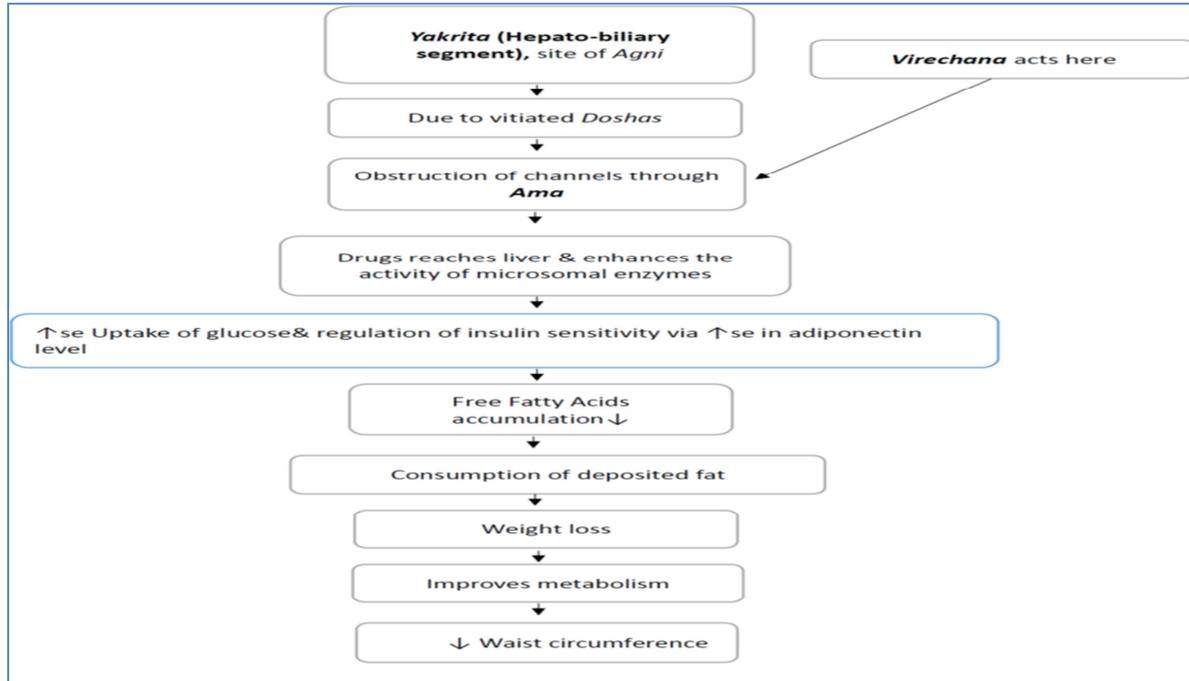

Figure 1: Mode of action of *Virechana Karma* in Metabolic Syndrome.

2) Discussion on mode of action of *Virechana Karma* in Metabolic Syndrome

Therefore, *Virechana Karma* acts on the liver, which is the seat for all microsomal enzymal activity. It improves metabolism which in turn reduces FFA accumulation. This in turn results into weight loss and reduction in waist circumference. All these conditions together help in pacifying symptoms of Metabolic Syndrome.

Conclusion

Thus on the basis of observations made in the present study it can be concluded that Metabolic syndrome is well defined and still evolving in biomedical sciences. It is as such not described in Ayurvedic classics, but it may be considered as the *Meda* dominant disorder has strong resemblance with *Prameha* and *Sthaulya/Medoroga*. Thus, it can be concluded that *Virechana* is a safe, effective and acceptable Treatment modality for Metabolic Syndrome.

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