



Clinical Evaluation of *Virechana* in the Management of Metabolic Syndrome- An Observational, Clinical Trial

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Conflicts of Interest: Nil

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ABSTRACT

INTRODUCTION- Metabolic Syndrome is a combination of several cardio-metabolic risk factors including Obesity, Hyperglycemia, hypertension & Dyslipidemia. They all collectively lead to the increase of the risk of Cardio-vascular disease. Over the years it has been associated with endothelial dysfunction, raised markers of chronic inflammation, insulin resistance and clotting dysregulation. Associated is an increase in obesity, type 2 diabetes, cardiac disease, stroke and death. As per Ayurveda, *Virechana* is the *Samshodhana* therapy that can be effective for treating metabolic syndrome.

AIMS & OBJECTIVES- To evaluate the role of *VirechanaKarma* in the management of Metabolic Syndrome.

MATERIAL & METHODS- The present study is a part of large scale population prospective, Observational Study. It is an Open Clinical Controlled Trial, with N=30, to be taken for this present study who were obese, under age group of 20-60 fulfilling criteria for inclusion, were included in the analysis of the present thesis.

RESULTS & CONCLUSION- Overall improvement of the *VirechanaKarma* in each parameter in which maximum improvement was observed in the Systolic Blood pressure i.e 87%, followed by 82.3% in Diastolic Blood pressure. In Blood Sugar, the percentile change was found 23.9%.

High Density Lipoprotein and Triglycerides has almost equal 37.7% and 37.6% respectively. In waist Circumference, relief was observed 78.8% percent and in weight, least percent relief was noticed i.e 6.5%.

KEY WORDS: Metabolic Syndrome, Cardio-Vascular Disease, *Virechana*.

Introduction

Metabolic Syndrome (MetS) is a multi-factorial disorder that associated with overweight & Obesity. The most common underlying risk factors for MetS, includes insulin resistance, abdominal Obesity (mainly visceral obesity). On frequency part, approximately 25% of the world's population has MetS & in north Indian population it is 40 percent respectively¹. Individuals who are

physically inactive, obese & genetically predisposed have greater risk of insulin resistance. The importance of metabolic syndrome is not just related to its high prevalence rate but also because it predicts the development of Diabetes & CVDⁱⁱ.

MetS is an assemblage of several inter related cardio metabolic factors often described by Obesity, Hypertension, dyslipidemia,

hyperglycemia & Insulin resistance^{iii,iv}. These conditions co-exist in an individual more than often might be expected by chance. MetS has been associated with an individual risk of developing type 2 DM (T2DM) and cardiovascular Disease (CVD)^v.

Non-alcoholic fatty liver disease is now recognized to be the hepatic component of the metabolic syndrome, which along with its individual components – particularly diabetes & elevated triglycerides, is the major risk factors of the development of the development of non-alcoholic fatty liver disease^{vi}. Non Alcoholic Steato hepatitis (NASH) may progress to cirrhosis, hepato-cellular carcinoma & liver failure.

In present Era, the *Ayurveda* is focusing on 2 concepts of diseases pathology^{vii}-

1) Due to in excess of sustenance

2) Due to lower than sustenance

Metabolic syndrome is the disease caused as a result of over nutrition due to distressed tissue metabolism. *Ayurveda* hypothesizes that metabolism of body is an indication of physiological state of *Agni* (biological fire) at different level in the body. Any disturbance or defection in the metabolism leads to choking of channels through a biological pathogenic factor named *Ama*, responsible as a part of generation in disorders like MetS. In terms of *Ayurveda*, *Santarpana Janya* vikara seems to have similarities with MetS. In Classical texts, it is presumed that vitiation of *Kapha doshas* followed by the other *doshas*, is the main initiating factor & involvement of *Meda* & other *dushya* is of special significance, because such a pathogenic feature of the disease indicates that MetS is a systemic disorder involving the whole body. Because of deep seated nature of disease & wide spread pathogenic involvement, it is difficult to treat. These basic considerations exhibit great resemblance with the contemporary modern understanding of MetS as known today. The chief component or *dhatu* which is get affected in *Santarpana janya Vyadhi* is *Meda*. It can be consider as chief *Dushya* in development of pathology. In the same way, confirmation of Central Obesity & dyslipidemia has been approved as the main

component of the basic ground of the disease. So, it is the prime most consideration to treat the disease at *Dushit Meda* level

Patients were assessed on the basis of objective parameters like routine and specific investigations such as Blood Sugar (fasting), Lipid profile, Blood pressure, Weight & Waist Circumference. Study was conducted on the basis of assessment & Diagnosis through NCEP ATP III and summarized as follows-

- Therapeutic procedure (*Virechana Karma*) in MetS is indicated in *CharakaSamhita* under the heading of *Santarpana Janya Rogo Ki Chikitsa*.
- MetS in *Ayurveda* can be put under the heading of *SantarpanaJanyaVyadhi* as described in *CharakaSamhitaSutraSthan* Chapter 23.
- Modern and *Ayurvedic* review of Disease was fully illustrated for the purpose of safe and effective management.
- Drugs used in therapeutic procedure (*VirechanaKarma*) were definite and have *Virechana* (purgative) property with different potency. They were used according to individuals pathogenesis of disease and individuals criteria of biological parameters especially *Agni* status and type of *Kostha*.
- Demography was thoroughly estimated to know the type of individuals having MetS and the types of disease present in specific habitat (Uttarakhand area). For this, the demographic proforma was made and estimated at last.
- After demographic estimation the results of therapeutic procedure were assessed in different individuals and different types of MetS (i.e the person has all criteria of MetS but with different proportion of parameters).
- Though, we have not taken any control drug for the estimation of therapy (because there is no specific standard drug has been established for MetS so far). We have analysed effect of *VirechanaKarma* at every assessment factor of diagnostic criteria of MetS.

- After Completion of Study results were analyzed and statistically estimated to evaluate the efficacy of *Virechana* in MetS.

AIMS AND OBJECTIVES:

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

Patients were selected on the basis of classical symptomatology of *Metabolic Syndrome* from OPD and IPD of Dept. Of Panchakarma, Hospital of Rishikul Campus, Uttarakhand Ayurved University, there after the patients were subjected for detailed clinical history & physical examination.

CRITERIA FOR SELECTION OF PATIENTS:

(A) INCLUSION CRITERIA-

1. Fasting glucose ≥ 100 mg/dl (or receiving drug therapy for hyperglycemia).
2. Blood pressure $\geq 130/85$ mmHg (or receiving drug therapy for hypertension).
3. HDL-C ≤ 40 mg/dl in men or ≤ 50 mg/dl in women (or receiving drug therapy for reduced HDL-C)
4. 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.
5. Age 20- 60 years
6. Patient fit for *Virechana* procedure with signs and symptoms of *Metabolic Syndrome*.

(B) EXCLUSION CRITERIA-

1. Age group < 20 years and more than 60 years
2. Uncontrolled Diabetes Mellitus (Type 2) with complications such as Nephropathy
3. Uncontrolled Hypertension or with complications.
4. Known case of IHD, CHF and any other vascular Disorders.

LABORATORY INVESTIGATIONS:

- 1) Routine hematological, urine examination

- 2) Blood sugar (Fasting)
- 3) Lipid Profile
- 4) Renal Function Test
- 5) X- ray Chest
- 6) E.C.G.
- 7) Liver Function Test (If required)

These investigations were carried out before, in between and after completion of therapy.

WITHDRAWAL CRITERIA:

1. Personal matters
2. Inter-current illness
3. Aggravation of complaints
4. He/She develops any serious adverse effect (necessitating hospitalization)

RANDOMIZATION AND BLINDING:

This is an open study.

The study protocol was reviewed and approved by an Institutional Review Board at the institution level. 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.

STUDY METHODOLOGY:

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.

RESULTS

As the NCEP ATP III is to be taken as a Diagnostic category for MetS. That's why objective parameters are to be taken for the Evaluation of Overall Effect of *Virechana* in MetS.

Table 1: Statistical Analysis of Overall Effect of *Virechana* in the objective parameters of Metabolic Syndrome.

Parameters	Mean		SD		t-Value	P-Value	% Effect	Result
	BT	AT	BT	AT				
Systolic BP	143.8	131.7	10.03	8.67	12.491	<0.01	87	Sig
Diastolic BP	93.5	84.2	8.53	6.55	7.423	<0.01	82.3	Sig
Raised Blood Sugar	113.9	110.7	30.69	35.70	.785	>0.05	23.9	NS
HDL	34.2	48.7	9.26	12.73	-5.927	<0.01	37.7	Sig
Triglyceride	184.5	128.1	42.91	41.75	9.902	<0.01	37.6	Sig
Waist Circumference	96.8	87.5	8.81	8.55	12.363	<0.01	78.8	Sig
Weight	90.1	84.2	10.88	10.53	10.968	<0.01	6.5	Sig

Since observations are quantitative, for statistical analysis paired-t-test is applied to check significance.

1. SYSTOLIC B.P

Before Treatment Mean Systolic BP was 143.8 after *Virechana*, it has been reduced to 131.7 with t-value of 12.491, along with p value <0.05 which is statistically significant.

2. DIASTOLIC B.P

Before *Virechana*, Mean Diastolic BP was 93.5 and after *Virechana* it has come on 84.2, with p value <0.05 i.e statistically significant.

3. RAISED BLOOD SUGAR

It is the only parameter where, SD after *Virechana* has increased from 30.69 to 35.70 respectively, with p value >0.05.

Hence, we can say that in parameter Raised Blood Sugar it statistically insignificant.

4. HDL (HIGH DENSITY LIPOPROTEIN)

Before *Virechana*, Mean HDL was 34.2 and after *Virechana* it has come on 48.7, with p value <0.01 i.e statistically significant.

5. TRIGYCERIDES

Before *Virechana*, mean was 184.5 and after *Virechana* was 128.1, with p value <0.01 that is statistically significant, with 30.6% relief.

6. WAIST CIRCUMFERENCE

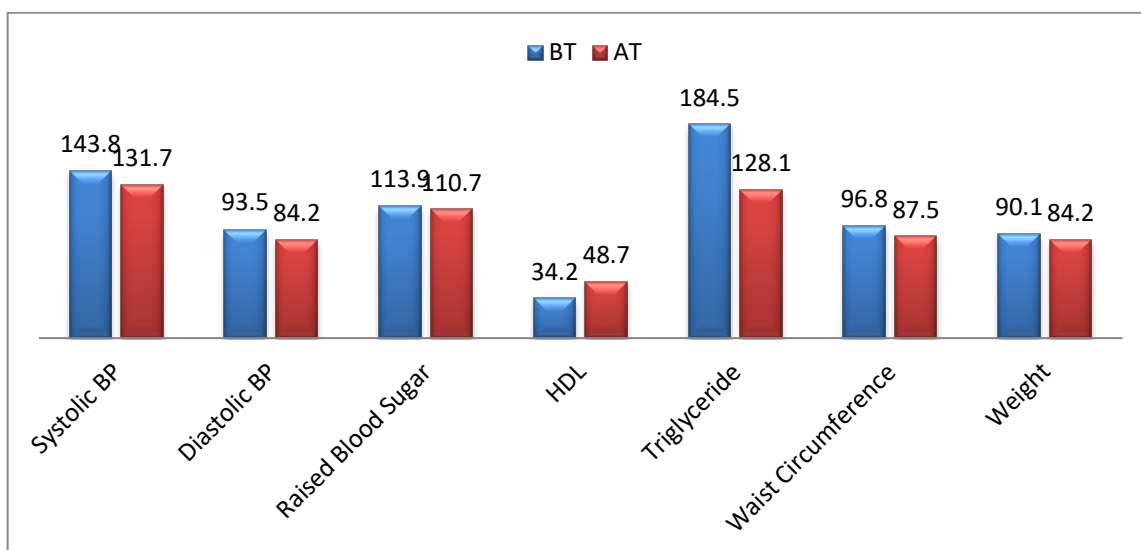
As central obesity is the mandatory parameter factor for the assessment of Metabolic Syndrome. Before *Virechana* it was observed that mean was 96.8 and after *Virechana* it was found 87.5 with p value <0.01 which is significant as per statistics.

7. WEIGHT

The basic and prime most factor to identify the diseased of metabolic syndrome as Obese. As Central obesity is the chief factor of Metabolic Syndrome and Obesity is directly equivalent to overweight.

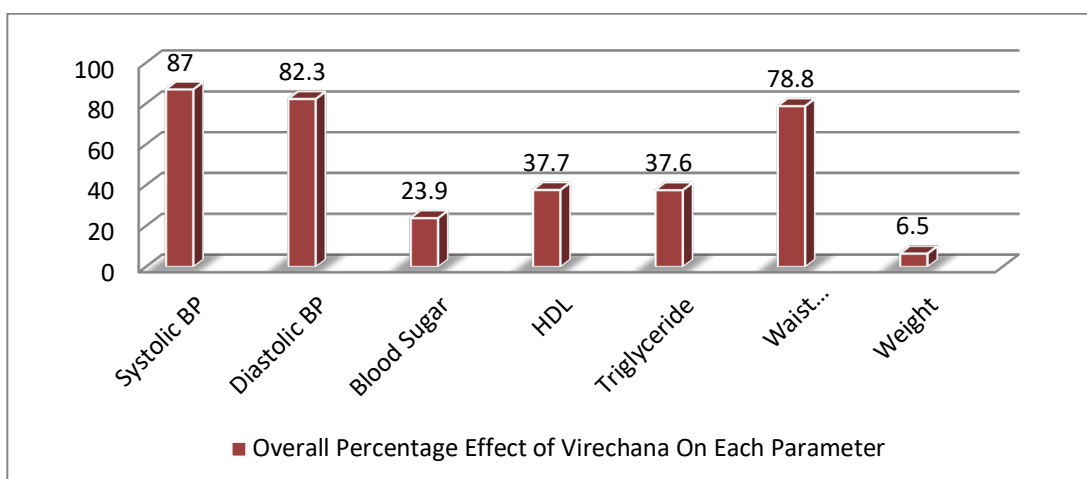
So the assessment of weight was also been showed in the data as before and after *Virechana* mean has reduced from 90.1 to 84.2 respectively.

The p value has been come out to be <0.01, so it can be said that it is also statistically significant.



From above table, we can observe that P value for all parameters are <0.05 except raised blood sugar. Hence, we can conclude that effect observed in all parameters are significant.

Overall Improvement of the Therapy in individual Parameter

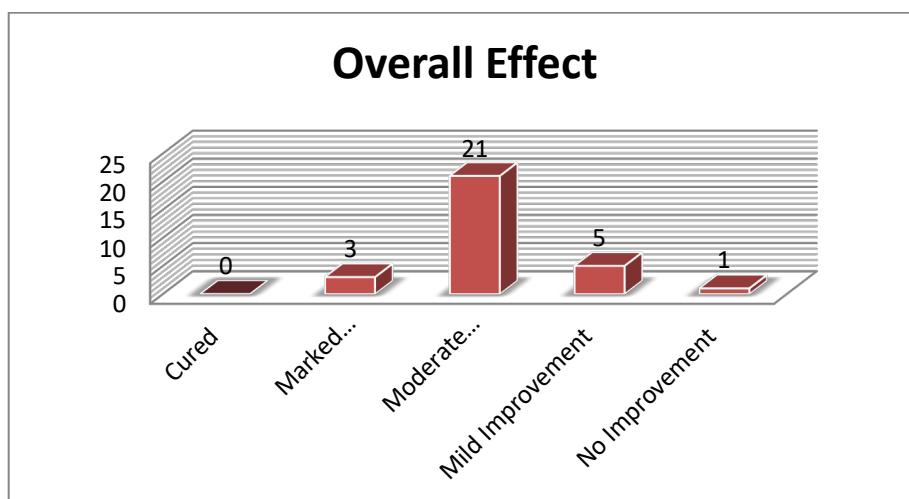


From this table, we can observe the overall improvement of the *VirechanaKarma* in each parameter in which maximum improvement was observed in the Systolic Blood pressure i.e 87%, followed by 82.3% in Diastolic Blood pressure. In Blood Sugar, the percentile change was found 23.9%.

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OVERALL RESULTS OF IMPROVEMENT

Overall Improvement	Frequency	Percentage
Cured	0	0.0
Marked Improvement	3	10.0
Moderate Improvement	21	70.0
Mild Improvement	5	16.7
No Improvement	1	3.3



Through above table, it has been clear now that 70% patients were received moderate improvement, rather than in mild improvement which was been found in only 5 patients.

ANALYSIS OF THE MODE OF THE ACTION OF VIRECHANA KARMA

The whole process of *VirechanaKarma* has 4 parts –

- a) *DeepanaPachana*
- b) *Snehpana*
- c) Preparation of *Virechana*
- d) *VirechanaKarma*

a) *DeepanaPachana*

‘*Deepana*’ the literal term define ‘to ignite’ & ‘*Pachana*’ the literal term define ‘to digest the already ingested food’. *Deepana-Pachana* is basically meant to use for ignition of *Agni* (biological fire). The main aim behind the *Deepana-Pachana* to increase the metabolism of body in such a level that it can utilize the maximum *Sneha* to be given in prospective study & help in digestion of improper digested food i.e. *Ama*. Medicines like *Agnitundi vati*, *Sanjeevani Vati* play important role in accomplishment of desired *Deepana-Pachana*.

b) *Snehpana*

The *Sneha* derived from ‘*Sneh*’ means ‘to ligate’. *Snehapana* plays an important role in therapeutic procedure (*Virechana*) as it decides vitality of the cells at membranous level. The lowest dose of *sneha* is given so as to assess the membranous functions of the cells and to increase the absorption of the *ghrita* at cellular level. It is well said, that after 7 days the *Snehapana* should be

stopped. The main reason behind the stoppage of *ghrita* after 7 days, that after 7 days, there is cessation of consumption of *ghrita* at micro-cellular level especially on permeability of cells.

In the meantime of *Snehapana*, the *ghrita* gets absorbed over the surface of cells with unwanted impurities or toxins with the effect of its ligating & propulsive properties. It may lead to ejection of toxins from intracellular fluid to extra cellular fluid.

c) Preparation of *Virechana*

The main purpose of preparation of *Virechana*, of 3 days gap prior to *Virechana* may be that given *sneha* would ligate & facilitate the movements of toxins in intramembranous flow and reach towards *Koshtha* i.e *Pachyamanashaya* (Liver).

It can be said as preparatory phase, in order to facilitate the excess FFAs towards liver.

d) *Virechana Karma*

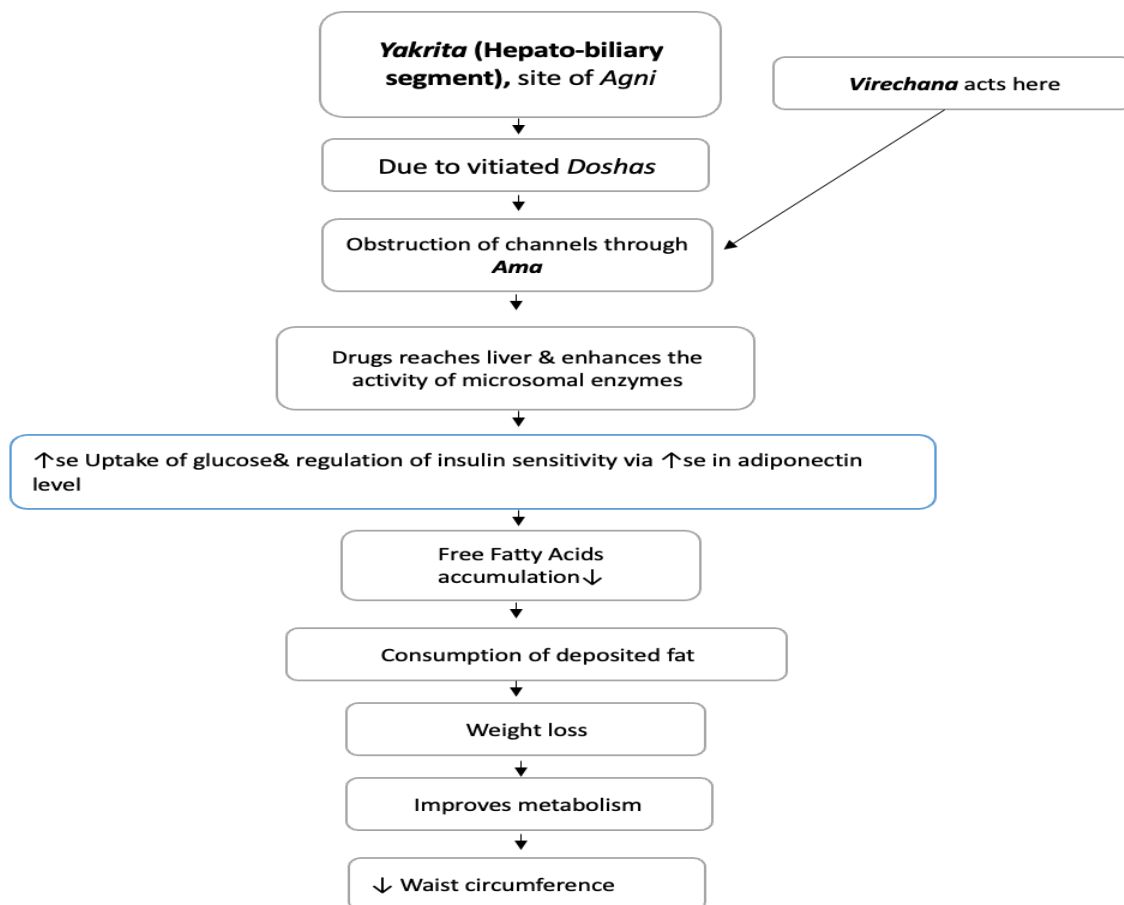
As per Ayurveda the, *Virechana* drug acts in *PachyamanaAwastha* i.e the digestion of drug is in progress. So, *Virechana* drugs start action in stomach and as result of the motor response through ganglionic plexus stimulation the peristaltic movements reach to a maximum level known as ‘**RushPeristalsis**’.

Due to this rush peristalsis pyloric part and the sphincter opens allowing the material to enter to the duodenum where local reflex

reactions along with the motor response through vagus stimulate duodenum to secrete more and more hormones such as cholecystokinin, hepatokinin etc. which encourages liver and pancreas to secrete much more digestive enzymes. During this digestive period, mucus secretion continues along with increased peristaltic movements. This second stage of digestion helps in the complete evacuation of *malas*, which contains fats, bacterial debris nitrogen compounds, acids, salts elements such as calcium, iron etc.

In the small intestine, the ‘Crypts of Luberkahn’ are stimulated and secrete more and more water. The bulk material expelled from the stomach combines with the enormous secretion of water. As a result, the osmotic pressure inside the small intestine is increased to a higher level. A pressure gradient established attracts much more water from the other areas of G.I.T which are having a lower osmotic pressure and the water content is increased once again and reaches its maximum level which is sufficient enough to push the material bulk downwards to the large intestine.

3. ILLUSTRATION OF THERAPEUTIC EFFICACY OF THE *VIRECHANAKARMA*



SUMMARY & CONCLUSION

- The present work entitled “**Clinical Evaluation of VirechanaKarma in the management of Metabolic Syndrome**” has been undertaken with aims to laid down scientific overview

on Metabolic syndrome as per conventional and *Ayurvedic* parlance. Beside this, it also aims to conduct an open clinical trial of *VirechanaKarma* in cases of metabolic syndrome.

- The incidence of MetS is alarmingly increasing in developed as well as developing countries including India. The observed fact is that the exact mechanism of complex pathways of MetS is not yet completely known but high calorie diet, faulty lifestyle, stressors, central obesity, endocrine disorders, aging along with genetic factors contribute a lot in the pathophysiology of MetS.
- It is believed that adipocytes of visceral fat increases plasma level of TNF- α and alters the level of others substances (adiponectin, leptin, resistin, PAI-1 etc) which plays a series of event of chronic inflammation that may lead to increased risk of developing hypertension, atherosclerosis, diabetes. Now it is well established fact that inflammatory component play a key role in the genesis of MS and other metabolic disorders. There is evidence that abdominal obesity is a key driving force behind a constellation of atherothrombotic inflammatory abnormalities linked to insulin resistance and MetS. It is also proposed that the amount of visceral adipose tissue and the liver fat contents are important factors responsible for the link between abdominal obesity and features of MetS.
- The emerging concept of MetS is strikingly resemblance with over-nutritional (*Santarpana Janya Vikaras*) disorders, which include *Sthaulya/Medoroga*, *Prameha* of *Ayurveda*.
- *Ayurveda* presumes that faulty dietary habits and lifestyle errors in accordance with genetic make of an individual alters functions of different sets of *Agni* (especially *Medodhatvagni*), which may leads to defective tissue metabolism at one side and formation of *Ama* (reactive antigenic factor) like substances at other sites.
- The *Samprapti* (pathogenesis) of this disease is presumed on specific *Dosha-Dushya* pattern besides, the special emphasis placed to the depletion of *Agni* as well as the vitiation of *Medas* (Lipids). Further, chronicity of disease, dyslipidemia, impaired function of cellular enzymes, and hyperglycemia leads to the formation of *Amalike* unwanted metabolic byproducts at respective levels of *Agnivyapara*. Probably this form of *Ama* is predominantly associated with *Dhatukshaya*, *Ojokshaya* and secondary *Vataprakopa*. It has a tendency to block the micro channels and derange the functions of immune system. Besides, the toxins if retained in the cell have capacity to destroy the cell or organ or system. This age-old ideas are now getting strong scientific support from the emerging concept of metabolic syndrome, Prediabetes, Insulin resistance and Type-2 DM, signifying the role of lipid disorder in the pathogenesis and dysmetabolic state (*Ama* state) in this disease. The literary holistic concept of *Ayurveda* provides significant lead to the understanding of MetS.
- In the present clinical work, *Virechana Karma* is selected as a treatment modality for the management of Metabolic Syndrome, which is *Kapha- Vata Shamak* & best *Shodhana* procedure.
- The Clinical Study included in this project based on the observation of 30 patients. These patients were worked up and investigated as per standard methods already described in the thesis. Critical care was taken in selection of patients as per the inclusion and exclusion criteria designed for this purpose and the patients were randomly recruited in single group.

REFERENCES

- ⁱSharma SK, Reddy EV, Sharma A, Kadhiravan T, Mishra HK, Sreenivas V, et al. Prevalence and risk factors of syndrome Z in urban Indians. *Sleep Med* 2010; 11 : 562-8.
- ⁱⁱMottillo, S., Filion, K. B., Genest, J., Joseph, L., Pilote, L., Poirier, P. et al. (2010). The metabolic syndrome and cardiovascular risk a systematic review and meta-analysis. *Journal of the American College of Cardiology*, 56, 1113-1132
- ⁱⁱⁱReaven, G. M. (1988). Banting lecture 1988. Role of insulin resistance in human disease. *Diabetes*, 37, 1595-1607.
- ^{iv}Balkau, B. & Charles, M. A. (1999). Comment on the provisional report from the WHO consultation. European Group for the Study of Insulin Resistance (EGIR). *Diabetic Medicine : A Journal of the British Diabetic Association*, 16, 442-443
- ^vGami, A. S., Witt, B. J., Howard, D. E., Erwin, P. J., Gami, L. A., Somers, V. K. et al. (2007). Metabolic syndrome and risk of incident cardiovascular events and death: a systematic review and meta-analysis of longitudinal studies. *Journal of the American College of Cardiology*, 49, 403-414.
- ^{vi}Westerbacka, J., Corner, A., Tiikkainen, M., Tamminen, M., Vehkavaara, S., Häkkinen, A. M. et al. (2004). Women and men have similar amounts of liver and intra-abdominal fat, despite more subcutaneous fat in women: implications for sex differences in markers of cardiovascular risk. *Diabetologia*, 47, 1360-1369.
- ^{vii}Pt. Kashinath Pandey, Dr. Gorakhnath Chaturvedi, Agnivesha, Charak, Dridhbala Samhita, Charak sutrasthan, chapter 23/40, Chaukhambha Bharti Academy, Varanasi, reprint year 2008