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Original Article

A Comparative Study on Monotherapy with Metformin, Vit-B3, Vit- D, Chromium Piconilate and Lifestyle Modification in development of Type II Diabetes Mellitus in the Metabolic Syndrome Patients

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ABSTRACT

Background: *Metabolic syndrome is a combination of multiple risk factors that increases an individual chance of developing cardiovascular or type II diabetes mellitus and most of people with metabolic syndrome have Insulin resistance, which elevates the risk of developing Type II diabetes mellitus. While the pathogenesis of the metabolic syndrome and each of its components is complex and not well understood, central obesity and insulin resistance are acknowledged as important causative factors. Most scrutinized literature was collected from different sources including PubMed. This study was carried out at Govt. Chhattisgarh Institute of medical sciences Bilaspur.*
Aim*: To compare the incidence of progression of metabolic syndrome into type II diabetes mellitus in patient who were put on one of the following treatments along with lifestyle modification :- Metformin, Chromium Piconilate ,Vitamin –D3 and Niacin (Vitamin. - B3).*
Methods: *The objective of this study recruited 250 patient, aged between 35 to 60 years, who fulfilled the inclusion and exclusion criteria of Metabolic syndrome as per study design.*
Results: *250 Participants was enrolled during 3 years of the study. 125 (50 %) male and 125 (50 %) Female were found metabolic syndrome. A total (8%) of patient were found incidence of progression of metabolic syndrome into Type II Diabetes Mellitus. In different group as Metformin group-(0%), Niacin group (6%), Vit-D3 group (0%), Chromium Piconilate group (16 %) and (18%) in the lifestyle modification group.*
Conclusions*: Metformin and Vit- D3 can reverse the effects of metabolic syndrome due to its broad effects on many of the components of metabolic syndrome; thus preventing diabetes and heart disease.*

Keywords: *Diabetes Mellitus, Metabolic Syndrome, Metformin*

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INTRODUCTION

Obesity is well recognised as the presence of excessive body fat. Depending on where the excess fat has been deposited divides obesity into subcutaneous (peripheral) or visceral (central) adiposity. It is the visceral fat which is believed to be most influential in cardiovascular risk.Visceral fat is generally deposited within the abdominal cavity surrounding the organs within. The metabolic dysfunction created by excess visceral fat mass influences multiple factors of disease risk. These have been identified from as far back as the 1920's and eventually grouped together into a cluster including abdominal obesity, dyslipidaemia, hyperinsulinaemia and hypertension, all of which may independently or collectively lead to an increase in the risk of cardiovascular disease. In 1988, Gerald Reaven presented the accumulation of his work at the "Banting" lecture identifying this group of risk factors as "Syndrome X" and proposing that insulin resistance was the underlying causative element. At this point he did not include obesity in his definition[1-4]

It is estimated that around 20-25 per cent of the world's adult population have the metabolic syndrome and they are twice as likely to die from and three times as likely to have a heart attack or stroke compared with people without the syndrome.

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In addition, people with metabolic syndrome have a fivefold greater risk of developing type 2 diabetes.[5]

The underlying cause of the metabolic syndrome continues to challenge the experts but both insulin resistance and central obesity are considered significant factors.[6,7] Genetics, physical inactivity, ageing, a pro inflammatory state and hormonal changes may also have a causal effect, but the role of these may vary depending on ethnic group.[8,9]

Worldwide definition

While the pathogenesis of the metabolic syndrome and each of its components is complex and not well understood, central obesity and insulin resistance are acknowledged as important causative factors.[10,11,12-14]

METHODS

It is an institutional open level randomized study which were carried out in the Department of Medicine and Pharmacology at Govt. Chhattisgarh Institute of Medical Science Bilaspur (C.G.). This study recruited 250 patient, aged between 35 to 60 years, who fulfilled the inclusion and exclusion criteria for Metabolic syndrome. Ethical clearance was approved from institutional ethical committee CIMS bilaspur. All participants were informed verbal assent and written consent to participation in the study prior to any form of testing. Participants were verbally informed of the nature and reason for each procedure, and given opportunity to ask questions. Participants were also reassured that they do not have to give any reason for withholding from participating in the testing procedures or withdrawing from the study.

A comprehensive list of inclusion and exclusion criteria is given below.

Inclusion criteria:

- Either gender within the age group of 35 to 60 years.
- Affected metabolic disorder accordingly. (International diabetes federation criteria)
- Overweight BMI > 30 kg/m^2.
- Nonsmoking with abdominal obesity (waist circumference > 80 cm in female and >90 cm in males.
- Dyslipidemia patient as per IDF criteria.
- Hypertension.

Exclusion criteria:

- Diabetes mellitus.
- <18 years either males or females.
- Pregnancy, or intention to become pregnant during the study

Recruitment Procedure:

After approval was done by the institutional ethical committee, patients were selected as per the criteria of metabolic syndrome and identified from the Department of Medicine at the Govt. Chhattisgarh institute of medical sciences, Hospital Bilaspur (C.G.). Interested participants were invited to attend the research centre CIMS, where the study was discussed in detail. If still willing to proceed they were included to sign a consent form prior to further interventions. Anthropometric measurements, blood pressure and baseline fasting bloods was taken to ensure they fulfilled the biochemical criteria for the study, followed a physical examination. The study was continued up to 3 months with follow-up.

Sample size :

250 patients either gender.

Our study included 250 subjects which was divided into 4 Groups: -

Group 1.

50 selected patients were given Metformin (Biguanides) 500 mg/day upto 3 months. (n=50)

Group 2.

50 selected patients were given Niacin (vit-B3)100 mg/day BD with meal up to 3 months (n=50)

Group 3.

50 selected patients were given vit-D3 (cholecalciferol) 1000 IU / day upto 3 months. (n=50)

Group 4.

50 selected patients were given chromium piconilate 500 micro-gram twice a day up to 3 month(n=50)

Group 5.

50 selected patients were in lifestyle modification upto 3 month(n=50)

Study Duration:

3 years

Anthropometric Parameters:

Body mass index (BMI), waist circumference (WC) and blood pressure, was recorded for all subjects. BMI was calculated by using the measured Height and weight {weight (kg) /height (m^2)}. WC was measured midway between the rib cage and the superior border of the iliac crest by using a milli-metric non-extensible and non-elastic measuring tape in midrespiration.

BP (mmHg) was recorded in either of the arm in the condition of complete physical and mental rest, in sitting position by using digital BP instruments.

RESULTS

- 250 Participants was enrolled during 3 years of the study.
- 125 (50 %) male and 125 (50%) Female was found metabolic syndrome.
- A total (8%) of patient was found incidence Type II Diabetes Mellitus among metabolic syndrome.
- Total 1.6 % of female was found incidence of Type II DM in among metabolic patient.
- Total 6.4 % of male was found incidence of Type II DM in among metabolic patient.

In different group result Type II DM was found like Metformin group-(0%), Niacin group (6%), Vit-D3 group (0%), Chromium Piconilate group (16%) and (18%) in the life style modification group.

Table 1: Positive and negative sample in ear swab

S/No	Group of drug	No. of Male	No. of Female	Incidence of Type II DM		Overall % ratio	% of Male	% of Female
				M	F			
1	Metformin	31	19	0	0	0 %	0	0
2	Vit-B3	22	28	02	01	6	0.8	0.4
3	Vit-D3	30	20	0	0	0	0	0
4	Chromium piconilate	19	31	07	01	16	2.8	0.4
5	Lifestyle modification	23	27	07	02	18	2.8	0.8
	Total	125	125	16	04	8	6.4	1.6

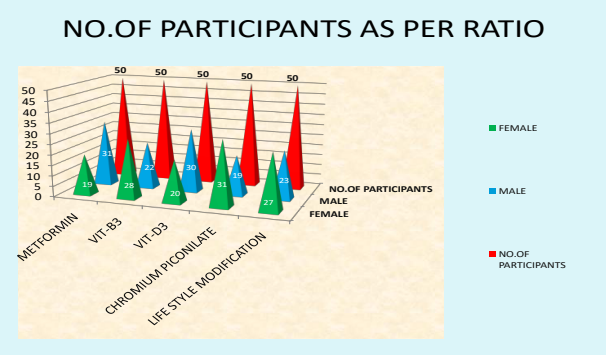

Fig 1 No. of Participants as per ratio

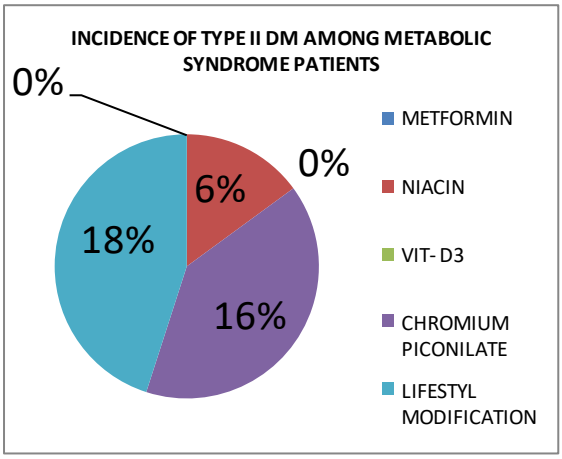

Fig 2: Incidence of Type II DM among Metabolic Syndrome

DISCUSSION

As per table number -01 total Participants was enrolled 250 during 3 years of the study. 125 **(50 %)** male and 125 **(50%)** Female was found metabolic syndrome. Total (**8%)** of patient was found incidence Type II Diabetes Mellitus among selected metabolic syndrome patients. Total 1.6 % of female was found incidence of Type II DM in among metabolic patient and 6.4 % of male was found incidence of Type II DM in among metabolic patient.

Obesity is associated with insulin resistance and the metabolic syndrome. Obesity contributes to hypertension, high serum cholesterol, low HDL-c and hyperglycaemia, and is independently associated with higher CVD risk.[6,10,11] The risk of serious health consequences in the form of type 2 diabetes, coronary heart disease (CHD) and a range of other conditions, including some forms of cancer, has been shown to rise with an increase in body mass index (BMI),[12] but it is an excess of body fat in the abdomen, measured simply by waist circumference, that is more indicative of the metabolic syndrome profile than BMI.[13-15] The International Obesity Task Force (IOTF) reports that 1.7 billion of the world's population is already at a heightened risk of weight-related, non-communicable diseases such as type 2 diabetes.[16]

In 2005, the International Diabetes Foundation (IDF) published new criteria modifying the ATP III definition aiming to establish a universal definition and method for clinical diagnosis[56].

They considered that abdominal obesity was highly correlated with insulin resistance and made the presence of abdominal obesity necessary for the diagnosis in addition to one of the four previously used criteria. IDF recognized the ethnic differences in the correlation between abdominal obesity and other MS risk factors and specified that waist measurement be specific to each racial group. With these recommendations abdominal obesity thresholds were set at waist circumferences 94 cm in men and 80 cm in women. For Asian populations, except Japan, thresholds were 90 cm in men and 80 cm in women; for Japanese they were 85 cm for men and 90 cm for women.[56]

Therefore disagreements persisted as to how best to define and diagnose MS until 2009, when the major institutions once more assembled to release an updated statement and definition which no longer placed abdominal adiposity as a requisite for the diagnosis, but once more reverted to a diagnosis being established on the presence of 3 of the 5 criteria[57]

CONCLUSION

Metformin and Vit- D3 can reverse the effects of metabolic syndrome due to its broad effects on many of the components of metabolic syndrome; thus preventing diabetes and heart disease.

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