3. MATERIALS AND METHODS

The study aims to assess the association of physical activity and metabolic syndrome. Information related to socio demographic profile, activity patterns and dietary habits was collected from middle aged urban people identified with metabolic syndrome on the basis of anthropometric measurements, blood pressure, blood glucose and lipid levels and compared with that of non metabolic syndrome subjects.

3.1 LOCALE OF THE STUDY

It was a hospital based study as subjects in the hospital are more accessible for detailed interviews than persons in the community. Hospital based studies allow detailed investigation of risk factors. The collection of secondary data and follow up data from medical records is also easier in a hospital environment. The following were the prerequisites in the selection of hospitals from where the subjects were drawn:

   a) Hospitals with a facility of preventive health check-ups.

   b) Consent of hospital authorities.

The following hospitals were approached and permission taken for conducting the study:

   MAX Hospital, Pitampura

   Jaipur Golden Hospital, Rohini

   City Hospital, Pusa Rood

   Fortis Jessa Ram Hospital, Karol Bagh.

   Fortis Hospital, Shalimar Bagh
3.2 SUBJECTS AND SAMPLE SIZE

The subjects were recruited from those coming to the OPDs of the selected hospitals for medical problems and for preventive health check-ups.

**Inclusion criteria for Metabolic Syndrome subjects was**

(1) Both males and females between the ages of 35-55 years.

(2) Willingness to participate in the study.

(3) Freshly diagnosed cases of metabolic syndrome on the basis of at least 3 components of metabolic syndrome as per the NCEP/ATP III criteria i.e.

- Elevated waist circumference: 101.6 cm or more for men; 88.9 cm or more for women.
- Elevated triglycerides: 150mg/dl or higher.
- Reduced HDL Cholesterol: less than 40 mg/dl in men, less than 50mg/dl in women.
- Elevated fasting blood glucose: 100 mg/dl or higher.
- Elevated blood pressure: 130/85 mmHg or higher.

**Exclusion criteria for Metabolic Syndrome subjects was**

- Subjects suffering from hormonal problems

**Inclusion criteria for Non Metabolic Syndrome subjects was**

- Subjects having less than 3 components of metabolic syndrome as per NCEP criteria.
Both males and females between the ages of 35-55 years.

Age and gender matched with MS subjects.

Willingness to participate in the study.

**Exclusion criteria for Non Metabolic Syndrome subjects was**

- Subjects suffering from hormonal problems

Purposive sampling was thus done to get a sample size of 750 cases of metabolic syndrome and 750 age and gender matched controls (non metabolic syndrome). The sample size was computed with the help of statistical approach using the formula:

\[(Z_{\alpha}+Z_{\beta})^2(p)(1-p)\]

\[e^2\]

\(Z_{\alpha}\): Level of Significance (5%)

\(Z_{\beta}\): Power (90%)

\(p\): Prevalence (40.1%)

\(e\): Error (10%)
3.3 DATA COLLECTION

Tools & Techniques

1. Anthropometric measurements like height, weight and waist circumference were taken using standardized techniques.

2. Subjects were examined for blood pressure.

3. Data relating to biochemical parameters like blood glucose and blood lipid profile were obtained from the hospital reports.

4. Suitable questionnaires were formulated to collect qualitative data regarding:
   
   - Demographic & baseline information including age, gender, education, occupation, socio-economic status, family profile.
   
   - Smoking and alcohol consumption.
   
   - Family history of the subjects for the components of metabolic syndrome.
   
   - Food consumption patterns like food habits and food preferences, meal patterns, eating out etc.
   
   - Routine daily physical activity and exercise pattern.
   
   - Occupational and leisure time physical activity.
   
   - Physical activity during the last 3-4 years including occupation, recreation and exercise patterns.
5. Quantitative data on the daily dietary intake was gathered by diet history and 24 hour recall method record combined with a food frequency questionnaire.

6. Quantitative data on physical activity levels of the subjects was collected using a standardized Physical Activity Questionnaire (PAQ).

7. Phenotypic markers were assessed.

3.4 ANTHROPOMETRIC ASSESSMENT

Anthropometry is the study of the measurement of the human body in terms of the dimensions of bone, muscle, and adipose (fat) tissue. Combined with the dietary and related questionnaire data, and the biochemical determinations, anthropometry is essential and critical information needed to assist in describing the data collected from the samples.

Anthropometry is a universally applicable, inexpensive and non invasive method to assess body size, weight and body proportions. These measurements can, in turn, be sensitive reflectors of overall health and nutritional well being of people. Two of the most fundamental and easily obtainable anthropometric measurements are length/height or stature and weight, although several other measurements are used such as linear measures or lengths; circumferences like mid upper arm circumferences (MUAC), head, chest, waist or hip circumferences and skin fold at various sites like triceps or sub scapular or bicep skin fold measurement. The choice of measurement at any stage of the life cycle should be the simplest and quickest measure, easiest to reproduce, while providing maximum information concerning the nutritional problems at that stage of life. The use of correct measuring equipment techniques and quality control is important. Averages of two to three measurements are recommended.
Anthropometric data is interpreted using reference values (local or international) for the measurements taken.

3.4(a) Body Weight Measurement

This is the most widely used, simple and reproducible anthropometric measurement for evaluation of nutritional status. Weight indicates the body mass that is the composite of whole body constituents like water, minerals, fat, proteins and bone. In relation to age, body weight indicates current nutritional status.

Technique:

- An electronic weighing scale was used for measuring body weight.
- Zero error of the weighing scale and its accuracy was checked before taking the weight.
- Individuals were weighed in minimal clothing without shoes.
- The individual was made to stand straight in the middle of the scale platform with arms hanging loosely on the sides and not leaning against or holding anything, while the weight was recorded.

3.4(b) Measurement of Height

This measurement reflects skeletal growth. Inadequate dietary intake can slow down linear growth rate and height deficit may be a measurement of duration of malnutrition. In relation to age, height deficit is indicative of chronic under nutrition. In nutritional anthropometry, maximum height of an individual is measured.

Technique:

- A non stretchable measuring tape, with sensitivity of 0.1 cm, mounted straight on a vertical wall was used for measuring height.
• Height was measured with the individual standing erect, without shoes on a level surface and looking straight ahead.
• The feet were put together, with heels, buttocks, shoulders and back of the head touching the vertical wall.
• The heels of the feet were placed together with both heels touching the base of the vertical board with the weight of the participant evenly distributed on both feet.
• The head piece of the measuring equipment was lowered upon the highest point of the head with just enough pressure to compress the hair.
• Measurements were read at the eye level.

3.4(c) Waist Circumference (WC)

Waist circumference provides a unique indicator of body fat distribution, which can identify patients who are at increased risk of obesity related cardio-metabolic disease, above and beyond BMI. WC measurement can sometimes provide additional information to help the clinician determine which patients should be evaluated for the presence of cardio-metabolic risk factors, such as dyslipidemia, and hyperglycemia. In addition, measuring WC can be useful in monitoring a patient’s response to diet and exercise treatment, because regular aerobic exercise can cause a reduction in both WC and cardio-metabolic risk, without a change in BMI (Klien et al, 2007).

Technique:

Waist circumference should be measured at a level midway between the lower rib margin and iliac crest with the tape all around the body in horizontal position. The tape should be loose enough to allow the observer to place one finger between the tape and the subject's body. Participants are asked to remove their clothes, except for light underwear. If this is not possible, for example due to cultural reasons, the alternative is to measure the circumference on the subject
without heavy outer garments and record this fact in the data collection form. Tight clothing, including the belt, should be loosened and the pockets emptied.

- Participants were made to stand with their feet fairly close together (about 12-15 cm) with their weight equally distributed on each leg.
- Participants were asked to breathe normally; the reading of the measurement was taken at the end of gentle exhaling to prevent subjects from contracting their abdominal muscles or from holding their breath.
- The measuring tape was held firmly, ensuring its horizontal position.

3.4(d) Body Mass Index

Body Mass Index (BMI) is calculated from a person's weight and height. BMI provides a reliable indicator of body fatness for most people and is used to screen for weight categories that may lead to health problems. This is a measure of the relative body fatness to evaluate risk factors associated with obesity. It is based on weight (in kg) with minimal clothing and height (in meters) without shoes (Garrow, 1978). BMI does not measure body fat directly, but research has shown that BMI correlates to direct measures of body fat, such as underwater weighing and dual energy x-ray absorptiometry (DXA). BMI can be considered an alternative for direct measures of body fat.

Calculating BMI is one of the best methods for population assessment of overweight and obesity. Because calculation requires only height and weight, it is inexpensive and easy to use for clinicians and for the general public and then compared with the guidelines (Table 3.1). The use of BMI allows people to compare their own weight status to that of the general population.

\[
\text{BMI} = \frac{\text{weight (kg)}}{[\text{height (m)}]^2}
\]
Table 3.1 The International BMI Classification of underweight, overweight and obesity for adults.

<table>
<thead>
<tr>
<th>Classification</th>
<th>BMI (kg/m²)</th>
<th>Principal cut-off points</th>
<th>Additional cut-off points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Underweight</td>
<td>&lt;18.50</td>
<td>&lt;18.50</td>
<td></td>
</tr>
<tr>
<td>Severe thinness</td>
<td>&lt;16.00</td>
<td>&lt;16.00</td>
<td></td>
</tr>
<tr>
<td>Moderate thinness</td>
<td>16.00 - 16.99</td>
<td>16.00 - 16.99</td>
<td></td>
</tr>
<tr>
<td>Mild thinness</td>
<td>17.00 - 18.49</td>
<td>17.00 - 18.49</td>
<td></td>
</tr>
<tr>
<td>Overweight</td>
<td>≥25.00</td>
<td>≥25.00</td>
<td></td>
</tr>
<tr>
<td>Pre-obese</td>
<td>25.00 - 29.99</td>
<td>25.00 - 27.49</td>
<td>27.50 - 29.99</td>
</tr>
<tr>
<td>Obese</td>
<td>≥30.00</td>
<td>≥30.00</td>
<td></td>
</tr>
<tr>
<td>Obese class I</td>
<td>30.00 - 34.99</td>
<td>30.00 - 32.49</td>
<td>32.50 - 34.99</td>
</tr>
<tr>
<td>Obese class II</td>
<td>35.00 - 39.99</td>
<td>35.00 - 37.49</td>
<td>37.50 - 39.99</td>
</tr>
<tr>
<td>Obese class III</td>
<td>≥40.00</td>
<td>≥40.00</td>
<td></td>
</tr>
</tbody>
</table>


BMI values are age-independent and the same for both sexes. However, BMI may not correspond to the same degree of fatness in different populations due, in part, to different body proportions. The health risks associated with increasing BMI are continuous and the interpretation of BMI grading in relation to risk may differ for different populations.

In recent years, there was a growing debate on whether there are possible needs for developing different BMI cut-off points for different ethnic groups due to the
increasing evidence that the associations between BMI, percentage of body fat, and body fat distribution differ across populations and therefore, the health risks increase below the cut-off point of 25 kg/m² that defines overweight in the current WHO classification.

The adequacy of the current international standard (WHO, 1998) for informing policy and interventions in some populations has been questioned due mainly to substantial inter population differences in the meaning of a given BMI (with respect to the level of body fatness, the associated level of health risk, or both) and in the range of BMI itself.

There have been two previous attempts to interpret the WHO BMI cut-offs in Asian and Pacific populations (WHO/IASO/IOTF, 2000; James et al, 2002) A proposal has been made to redefine the classification of obesity using BMI for Asian population (Table 2) as there is now evidence that the increased risks of co-morbidities with obesity occurs at lower BMIs in Asians (Table 3.2). The recommendation is however based on two studies - in Hong Kong (Ko et al, 1999) and in Singapore (Deurenberg et al, 2000). WHO convened another expert consultation in Singapore in 2002 to address the debate on interpretation of recommended BMI cut-off points for determining overweight and obesity in the Asian population.
Table 3.2: Classification of weight status according to BMI in Asian Adults

<table>
<thead>
<tr>
<th>Classification</th>
<th>BMI (kg/m²)</th>
<th>Risk of co-morbidities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Underweight</td>
<td>&lt; 18.5</td>
<td>Low (but risk of other clinical problems increased)</td>
</tr>
<tr>
<td>Normal range</td>
<td>18.5 – 22.9</td>
<td>Average</td>
</tr>
<tr>
<td>Overweight:</td>
<td>&gt; 23.0</td>
<td></td>
</tr>
<tr>
<td>At Risk</td>
<td>23.0 – 24.9</td>
<td>Increased</td>
</tr>
<tr>
<td>Obese class I</td>
<td>25.0 – 29.9</td>
<td>Moderate</td>
</tr>
<tr>
<td>Obese class II</td>
<td>&gt; 30.0</td>
<td>Severe</td>
</tr>
</tbody>
</table>


The population level of BMI cut-off points is to identify risks of adverse health outcomes associated with different levels of body composition, so as to inform and trigger policy action, facilitate prevention programmers and to measure the impact of interventions. BMI cut-off points are also used for epidemiological purposes to help in determination of the etiology of diseases. For clinical applications, population specific cut-off points will need to be determined by countries as most appropriate and should be used with an individual’s clinical history and other clinical measurements (e.g. waist circumference and presence of other related factors). Ethnic-specific cut-off points may not be useful as it is likely to create great confusion in health promotion and disease prevention and management.

In the present study, the subjects were classified according to the BMI categories for Asian adults.
3.5 BLOOD PRESSURE

Blood pressure is a force of blood against the arteries. High blood pressure is a serious condition that can lead to coronary heart disease, heart failure, stroke, kidney failure, and other health problems. Although this condition usually has no symptoms, it can damage the heart, blood vessels and kidneys.

3.5(a) Blood Pressure Assessment

Blood pressure was measured as systolic and diastolic pressures. "Systolic" refers to blood pressure when the heart beats while pumping blood. "Diastolic" refers to blood pressure when the heart is at rest between beats.

Table 3.3 shows normal blood pressure numbers for adults. It also shows which numbers put an individual at greater risk for health problems.

Table 3.3 Categories for Blood Pressure Levels in Adults (measured in millimeters of mercury, or mmHg)

<table>
<thead>
<tr>
<th>Category</th>
<th>Systolic</th>
<th>Diastolic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>Less than 120</td>
<td>Less than 80</td>
</tr>
<tr>
<td>Pre hypertension</td>
<td>120–139</td>
<td>80–89</td>
</tr>
<tr>
<td>High blood pressure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stage 1</td>
<td>140–159</td>
<td>90–99</td>
</tr>
<tr>
<td>Stage 2</td>
<td>160 or higher</td>
<td>100 or higher</td>
</tr>
</tbody>
</table>

- The ranges in the table apply to most adults (aged 18 years and older) who do not have short-term serious illnesses.
• All levels above 120/80 mmHg raise the risk, and the risk grows as blood pressure numbers rise.

Technique

• Measurements were taken using a sphygmomanometer.
• Patients are seated quietly for at least 5 minutes in a chair with their backs supported and their arms bared and supported at heart level.
• The cuff is placed so that the lower edge is 3 cm above the elbow crease and the bladder is centered over the brachial artery.
• The arm should be bare and supported with the BP cuff at heart level, as a lower position will result in an erroneously higher SBP and DBP.
• There should be no talking, and patients’ legs should not be crossed. At least three measurements should be taken in the same arm with the patient in the same position.

The blood pressure of the subjects was measured thrice at an interval of 5-10 minutes as per the above technique and the average of these readings was calculated.

3.6 BIOCHEMICAL ASSESSMENT

According to third report of National Cholesterol Education Program (NCEP) expert report (ATPIII) (2008), metabolic syndrome is defined as having three or more of the following abnormalities:-

• Elevated waist circumference: 90 cm or more for men; 80 cm or more for women.
• Elevated triglycerides: 150mg/dl or higher.
- Reduced HDL Cholesterol: less than 40 mg/dl in men, less than 50 mg/dl in women.

- Elevated fasting blood glucose: 100 mg/dl or higher.

- Elevated blood pressure: 130/85 mm Hg or higher.

In the present study, values for the biochemical parameters of the subjects viz fasting blood glucose, triglycerides and HDL cholesterol were collected from the hospital reports.

3.6(a) Fasting Blood Glucose Test

A fasting blood glucose test, also called a fasting plasma glucose test, measures blood glucose levels without food for at least eight hours. It is reliable and the results are not affected by age or the amount of physical activity. Many doctors prefer the fasting plasma glucose test because it is easy, fast and inexpensive.

Test Procedure

- To prepare, the individual must not eat for at least eight hours before the test.

- The next morning, a healthcare provider takes a single sample of blood and sends it to a lab for analysis.

- Fasting blood glucose tests done in the morning, rather than the afternoon, appear to be more accurate in diagnosing diabetes.

- Normal blood glucose levels are less than 100 mg/dl.

- The fasting blood glucose test is commonly used to detect diabetes mellitus.

- Levels between 100 and 126 mg/dl are referred to as impaired fasting glucose or pre-diabetes.

- Diabetes is typically diagnosed when fasting blood glucose levels are 126 mg/dl or higher.
3.6(b) Blood Lipid Profile

The lipid profile is a group of tests that are often ordered together to determine risk of coronary heart disease. They are tests that have been shown to be good indicators of whether someone is likely to have a heart attack or stroke caused by blockage of blood vessels or hardening of the arteries (atherosclerosis). The lipid profile typically includes:

- Total cholesterol
- High density lipoprotein cholesterol (HDL-C) often called good cholesterol
- Low density lipoprotein cholesterol (LDL-C) often called bad cholesterol
- Triglycerides

An extended profile may also include:

- Very low density lipoprotein cholesterol (VLDL-C)
- Non-HDL-C

Sometimes, the report includes additional calculated values such as the Cholesterol/HDL ratio or a risk score based on lipid profile results, age, sex, and other risk factors.

3.6(c) High Density Lipoprotein (HDL)

Each bit of HDL cholesterol is a microscopic blob that consists of a rim of lipoprotein surrounding a cholesterol center. High density lipoproteins are a combination of fats (lipids) and proteins in which lipids are transported in the blood. HDLs transport cholesterol from the tissues of the body to the liver, so the cholesterol can be eliminated in the bile. HDL cholesterol is therefore considered the 'good' cholesterol.
3.6(d) Triglycerides (TG)

Triglycerides are the chemical form in which most fat exists in food as well as in the body. They are also present in blood plasma and, in association with cholesterol, form the plasma lipids.

Excess of triglycerides in plasma is called hypertriglyceridemia. It is linked to the occurrence of coronary artery disease in some people. Elevated triglycerides may be a consequence of other disease, such as untreated diabetes mellitus. Like cholesterol, increases in triglyceride levels can be detected by plasma measurements. These measurements are made after an overnight food and alcohol fast.

3.7 QUESTIONNAIRE

A questionnaire is a set of progressive questions spanning from general to specific information that is commonly used to gather information from the respondents. This could be self-administered or could be administered by an interviewer. It can be a structured questionnaire that poses definite and concrete questions that are prepared well in advance. When the questions are prepared on the spot by the researcher, it is called the unstructured questionnaire.

In any type of a questionnaire, there can be two types of questions- open ended or close ended. In open ended questions, the respondent is given some space in the questionnaire where he/she can write the response in answer to the questions. These questions are usually related to experiences or other aspects which cannot be classified under options. These are usually placed at the end of the questionnaire.

The close ended questionnaires are the ones in which exhaustive options are given to the respondents to choose from. These are like objective questions and are usually placed in the beginning of the questionnaire.
The type of questionnaire used in the study was a structured one where the questionnaire was divided into 4 parts – demographic profile, health profile, physical activity profile and dietary profile. One separate standardized questionnaire was also used to assess the physical activity level of the subjects. These questions were provided with exhaustive answers to be selected from.

The questionnaire was designed to collect:

- Baseline information like age, sex, occupation, education, family size, family income, family profile, socio-economic status.
- Family history of metabolic syndrome components.
- Health profile.
- Physical activity profile like type and duration of physical activity, previous physical activity, change in physical activity over the previous years, recreational activities.
- Dietary patterns, number of meals, food preferences, type of food consumed, consumption of fruits and vegetables, sweet beverages, type of fat, eating out pattern.
- Smoking and alcohol consumption.

### 3.8 DIETARY ASSESSMENT

Diet is a vital determinant of health and nutritional status of people. The dietary habits of individuals/ families/ community vary according to socio-economic factors, regional customs and tradition. Precise information on food consumption pattern of people, through application of appropriate methodology is often needed not only for assessment of nutritional status of people but also for elucidating the relationship of nutrient intake with deficiency as well as degenerative disease (Bamji, 2004).
In the present study, data on the dietary intake was gathered by:

1. 24 hour recall method
2. Diet history method
3. Food frequency questionnaire

**3.8(a) 24-hour dietary recall method**

24-hour dietary recall method is to gather information on the usual eating patterns of the subjects. For the 24-hour dietary recall, the respondents were asked to remember and report all the foods and beverages consumed in the preceding 24 hours.

24 hour dietary recall method is a reliable source of collecting data as it helps to analyze the diet pattern and the quantity of food consumed by the subjects. It is based on the food and amounts actually consumed by the individual on their meals in a day. Ideally, interviewers would be dietitians with education in foods and nutrition; however, non-nutritionists who have been trained in the use of a standardized instrument can be effective. All interviewers should be knowledgeable about foods available in the marketplace and about preparation practices, including prevalent regional or ethnic foods. The interview is often structured, usually with specific probes, to help the respondent remember all foods consumed throughout the day. An early study found that respondents with interviewer probing reported 25% higher dietary intakes than did respondents without interviewer probing. Probing is especially useful in collecting necessary details, such as how foods were prepared. It is also useful in recovering many items not originally reported, such as common additions to foods (e.g., butter on toast) and eating occasions not originally reported (e.g., snacks and beverage breaks). However, interviewers should be provided with standardized neutral probing questions so as to avoid leading the respondent to specific answers...
when the respondent really does not know or remember. For full information, interviewer must ask open-ended questions and close ended too. One must choose key questions and use memory aids to probe the answer.

The interviewer-administered 24-hour recall has long been regarded as the optimal methodology because it provides the highest-quality and least biased dietary data for a single day. This method allows collection of detailed intake and portion sizes, and because the data collection occurs after consumption, this method does not affect an individual's food choices on a given day.

The purpose of this method is to get an accurate and complete listing of all food and drinks that the client had consumed (Walter, 1998). There are many advantages to the 24-hour recall. An interviewer administers the tool and records the responses, so literacy of the respondent is not required. Because of the immediacy of the recall period, respondents are generally able to recall most of their dietary intakes. Because there is relatively little burden on the respondents, those who agree to give 24-hour dietary recalls are more likely to be representative of the population than are those who agree to keep food records. Thus, the 24-hour recall method is useful across a wide range of populations. In addition, interviewers can be trained to capture the detail necessary so that the foods eaten by any population can be researched later by the coding staff and coded appropriately.

3.8(b) Dietary History

The term “diet history” is used in many ways. In the most general sense, a dietary history is any dietary assessment that asks the respondent to report about past diet. Several investigators have developed diet history instruments that provide information about usual food intake patterns beyond simply food frequency data (Landig, 1998). Some of these instruments characterize foods in more detail than is allowed in food frequency lists (e.g., preparation methods and
foods eaten in combination), and some of these instruments ask about foods consumed at every meal (Kohlmeier, 1997). The term “diet history” is therefore probably best reserved for dietary assessment methods that are designed to ascertain a person’s usual food intake in which many details about characteristics of foods as usually consumed are assessed in addition to the frequency and amount of food intake.

3.8(c) Food Frequency Questionnaire

The food frequency approach (Zulkifli, 1992) asks respondents to report their usual frequency of consumption of each food from a list of foods for a specific period of time. Information is collected on frequency and sometimes portion size, but little detail is collected on other characteristics of the foods as eaten, such as the methods of cooking or the combinations of foods in meals. To estimate relative or absolute nutrient intakes, many FFQs also incorporate portion size questions, or specify portion sizes as part of each question. Overall nutrient intake estimates are derived by summing, over all foods, the products of the reported frequency of each food by the amount of nutrient in a specified (or assumed) serving of that food to produce an estimated daily intake of nutrients, dietary constituents, and food groups.

The appropriateness of the food list is crucial in the food frequency method. The full variability of an individual’s diet, which includes many foods, brands, and preparation practices, cannot be fully captured with a finite food list. Obtaining accurate reports for foods eaten both as single items and in mixtures is particularly problematic.

Strengths of the FFQ approach are that it is inexpensive to administer and process and aims to estimate the respondent’s usual intake of foods over an extended period of time. Unlike other methods, the FFQ can be used to circumvent recent changes in diet (e.g., changes resulting from disease) by
obtaining information about individuals’ diets as recalled about a prior time period. Retrospective reports about diet nearly always use a food frequency approach. Food frequency responses are used to rank individuals according to their usual consumption of nutrients, foods, or groups of foods. Nearly all food frequency instruments are designed to be self-administered, require 30 to 60 minutes to complete depending on the instrument and the respondent, and are either optically scanned paper versions or automated to be administered electronically (Nutrition Quest, 2007; Matths, 2007). Because the costs of data collection and processing and the respondent burden are typically much lower for FFQs than for multiple diet records or recalls, FFQs have become a common way to estimate usual dietary intake in large epidemiological studies.

3.9 ASSESSMENT OF PHYSICAL ACTIVITY

The choice of method to measure physical activity is dependent on the aspect of physical activity which is central to the research question. Decisions about the likely effect of season or days of the week may influence the choice of method or the length of the assessment period. A combination of methods may be required to obtain the desired outcomes. The dimensions of physical activity include frequency, intensity, duration and type. The domains in which physical activity occur include leisure time, occupational, transport and household / garden chores. The ideal physical activity assessment method would measure all dimensions in all domains.

Physical Activity can be assessed by several methods including diaries, time and motion studies, motion sensors, and stable isotope methods. These methods are however costly. In contrast, questionnaires are easy to administer and cost effective. Physical activity questionnaires (PAQs) are the most widely used self-report instrument to assess physical activity and have been used extensively in research. Self-report measures include self or interviewer administered. There
are large numbers of physical activity questionnaires used in industrialised countries. Many of these questionnaires focus on specific components of physical activity, often leisure time activity (Lee, 1995; Haskell, 1980), together with some components of 24 hour energy expenditure.

According to Bharathi, Sandhya and Vaz (2000), there are several problems that confound the assessment of physical activity profile in India using the existing questionnaires. A study was hence devised by them to develop and test a Physical Activity Questionnaire (PAQ) that would overcome the constraints of the existing questionnaires. The questionnaire estimates 24 hour energy expenditure as well as components of occupational and discriminatory leisure time activity. It provides a tool for the assessment of physical activity pattern in urban middle class Indians. In this questionnaire, Information is collected for daily, weekly and monthly physical activity.

Daily physical activities are assessed under three categories:-

(1) Sleep

(2) Occupational activity

(3) Discretionary leisure time physical activity.

This questionnaire has subsequently been used for a study on “Physical activity and risk of coronary heart diseases in India” by Rastogi (2004) in New Delhi and Bangalore.

Assessment of physical activity for the present study was done using this questionnaire. Diary method was used to record physical activity for

1. Two working days

2. One non-working day.
The analytical procedure used in the assessment of the physical activity includes assessment of:

- **BASAL METABOLIC RATE**

  Basal Metabolic rate was calculated from WHO recommended age & gender specific regression equations that include height & weight as predictor variables.

<table>
<thead>
<tr>
<th>AGE (years)</th>
<th>MEN</th>
<th>WOMEN</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-30</td>
<td>15.057kg+692.2</td>
<td>14.818kg+486.6</td>
</tr>
<tr>
<td>30-60</td>
<td>11.472kg+873.1</td>
<td>8.126kg+845.6</td>
</tr>
<tr>
<td>&gt;60</td>
<td>11.711kg+587.7</td>
<td>9.082kg+658.5  (FAO, 2004)</td>
</tr>
</tbody>
</table>

- **ENERGY EXPENDITURE**

  24 hour energy expenditure is calculated as the sum of energy expenditure of all reported activities computed for a single day.

  Energy Expenditure: \( \text{BMR/min} \times \text{MET} \times \text{duration of the activity in min.} \)

- **PHYSICAL ACTIVITY LEVEL (PAL)**

  \[
  \text{PAL} = \frac{\text{24 hour energy expenditure}}{\text{Basal metabolic rate}}
  \]

  Cut offs for PALs are:

  1. Sedentary - 1.40-1.69
  2. Moderately - 1.70-1.99
3.10 GOLD STANDARD FOR VALIDATION OF ASSESSMENT OF PHYSICAL ACTIVITY

Physical Activity can be assessed on the basis of total energy expenditure which can be estimated by several methods. One of the methods is the factorial method which involves the calculation of PAL from data collected by the Physical activity questionnaires (PAQs) which is a feasible approach for determining energy expenditure (EE) estimation in large populations.

Another method which was accepted by WHO was DWL as the criterion method for free living energy expenditure determination. Accelerometry is another physical activity monitoring technique with the basic objective of measuring the free living physical activity pattern. This technique is also being used in studies on energy expenditure assessment and monitoring sleeping patterns (Singh et al, 2010). The portable devices based on accelerometry using motion sensors are used for their convenience and improved precision.

In the present study, an accelerometry based Actical system was used to validate the assessment of physical activity levels (PAL) using data collected by PAQ. For application of Actical device, 9 subjects of the same age group as that of the study were selected. The calibrated water proof Actical activity monitoring device was put on the subjects’ wrists for three days after uploading the required information on age, height, weight etc. and the data was analyzed using Actical software. For the same three days, information on the daily physical activity of these subjects was also gathered by the PAQ used for the study. The total energy expenditure as calculated by the two methods was then compared and the PAL values are given in Table 3.4.
Table 3.4 PAL values as per Physical Activity Questionnaire and Actical Device

<table>
<thead>
<tr>
<th>S.NO OF SUBJECTS</th>
<th>PAL VALUES AS PER PHYSICAL ACTIVITY QUESTIONNAIRE (PAQ)</th>
<th>PAL VALUES AS PER ACTICAL DEVICE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>1.92 Moderate</td>
<td>1.97 Moderate</td>
</tr>
<tr>
<td>2.</td>
<td>1.57 Sedentary</td>
<td>1.68 Sedentary</td>
</tr>
<tr>
<td>3.</td>
<td>1.80 Moderate</td>
<td>1.87 Moderate</td>
</tr>
<tr>
<td>4.</td>
<td>1.50 Sedentary</td>
<td>1.61 Sedentary</td>
</tr>
<tr>
<td>5.</td>
<td>1.75 Moderate</td>
<td>1.89 Moderate</td>
</tr>
<tr>
<td>6.</td>
<td>1.5 Sedentary</td>
<td>1.57 Sedentary</td>
</tr>
<tr>
<td>7.</td>
<td>1.73 Moderate</td>
<td>1.78 Moderate</td>
</tr>
<tr>
<td>8.</td>
<td>1.71 Moderate</td>
<td>1.84 Moderate</td>
</tr>
<tr>
<td>9.</td>
<td>1.54 Sedentary</td>
<td>1.57 Sedentary</td>
</tr>
</tbody>
</table>

The above data indicates that PAL values as calculated from data collected by PAQ and Actical method gave similar results (within 10%). This validates the questionnaire and its applicability.
3.11 CLINICAL ASSESSMENT

3.11(a) Phenotypic Markers of Metabolic Syndrome

The metabolic syndrome (MS) and type 2 diabetes mellitus (T2DM) are common in Asian Indians. Simple yet reliable phenotypic markers are needed for early detection of MS in Asian Indians. Buffalo hump (excess fat deposition in dorsocervical region) is frequently observed in Cushing’s syndrome, and HIV-associated lipodystrophy is associated with insulin resistance and other features of MS (Mallon et al, 2005).

Double chin (excess fat deposition under the chin) is often seen in obese individuals and is reported to be a significant predictor of diabetes in patients of familial partial lipodystrophy (FPL) (Haque et al, 2003). Skin tags (acrochordon) and xanthelasma as potential markers of impaired carbohydrate metabolism and dyslipidemia, respectively, have been suggested (Demer et al, 2002) but have not been systematically investigated.

In the present study, phenotypic markers were evaluated in the following manner for objective evaluation.

1. **Buffalo Hump**

   For assessment of buffalo hump, the subject stands against the wall, feet/shoulders and spine in line with the wall. It is present if the angle between the perpendicular line drawn in midline from occipital prominence to seventh cervical vertebra and the tangential line aligned to the angle of fat pad is <100.

2. **Double Chin**

   A double chin is defined as a layer of subcutaneous fat around the submandibular area that is visible below the original chin with patient sitting with eyes looking straight in front and neck in normal position.
3. Acrochordon
Skin tag or acrochordon is defined as skin growth projecting from the skin surrounding the neck and chest, raised above the surrounding skin with or without a stalk.

4. Xanthelasma
Xanthelasma is defined as raised yellowish plaque that is usually present near the inner canthus of the eyelid or surrounding eye in any direction (Mishra et al, 2007).

3.12 DATA ANALYSIS
The data collected was subjected to both qualitative and quantitative analysis. The data was analyzed in terms of age, gender, income, educational background, exercise pattern, dietary habits, physical activity level, phenotypic markers and other relevant variables which directly or indirectly may be related to metabolic syndrome. The responses obtained on the questionnaire were transformed to master code sheets for easy interpretation. All the data was entered on to excel worksheets. Data were recorded, validated and stored using the Statistical Package for the Social Sciences (SPSS), Windows software, version 19.0

BASIC DESCRIPTIVE STATISTICS
Simple associations were assessed with frequency tables. The data was presented as absolute numbers and percentages.

The level of significance was determined by a p value, the probability that an observed result was due to chance alone. The null hypothesis was rejected if p value was less than alpha value (level of significance). Alpha value is defined as the probability of rejecting the null hypothesis when it is true. The alpha value chosen was 0.01 or 0.05. At this level, 1% or 5% of type I error (false rejection of
null hypothesis) is allowed in the study design. SPSS provided the actual p value, accurate to 1 or 5 decimal places.

**ANOVA (Analysis of Variance)**

A statistical analysis tool that separates the total variability found within a data set into two components: random and systematic factors. The random factors do not have any statistical influence on the given data set, while the systematic factors do. The ANOVA test is used to determine the impact independent variables have on the dependent variable in a regression analysis. It is used to determine whether there are any significant differences between the means of two or more independent groups.

In the present study, ANOVA was used to find out the significance difference in the mean values of components of metabolic syndrome by addition of each component.

**ANOVA Post – hoc test**

Post hoc tests are designed for situations in which the researcher has already obtained a significant omnibus F-test with a factor that consists of three or more means and additional exploration of the differences among means is needed to provide specific information on which means are significantly different from each other. The most widely used post hoc test is Tukey's Honestly Significant Difference or HSD test. There are many types of post hoc tests all based on different assumptions and for different purposes. Tukey's HSD is a versatile, easily calculated technique.
MEASUREMENT OF STRENGTH OF ASSOCIATION

To measure the strength of association for case control studies, the ‘ODDS RATIO’ (OR) is commonly used. Calculation of the odds ratio enables the assessment of the strength of association between the outcome and the identifiable risk factor. OR = 1 indicates that the concerned factor is not a risk.

The odds ratio provides a measure of the strength of relationship between two variables, most commonly as exposure and a dichotomous outcome. It is most commonly used in the case-control study where it is defined as “the ratio of the odds of being exposed in the group with the outcome to the odds of being exposed in the group without the outcome”. The odds ratio was calculated with 99% or 95% confidence interval (CI).

In the present study, odds ratio was calculated regarding metabolic syndrome and physical activity level, and each individual component of metabolic syndrome with physical activity level.

KARL PEARSON’S CORRELATION

Correlation analysis is a statistical relation between two or more variables such that systematic changes in the value of one variable are accompanied by systematic changes in the other. It is used to evaluate the strength of the relations between variables. Karl Pearson’s Correlation is one of the most widely used correlations in practice. It is denoted by symbol ‘r’. this method is only applied where the deviations of items are taken from actual means and not from assumed means. The Pearson correlation is +1 in the case of a perfect positive linear correlation, −1 in the case of a perfect negative linear correlation.
In present study, Karl Pearson Correlation was used to find out a negative or positive correlation of each components of metabolic syndrome with each other, BMI and Physical Activity Level (PAL).

**REGRESSION ANALYSIS**

Regression analysis is a statistical tool for the investigation of relationships between variables. Usually, the investigator seeks to ascertain the causal effect of one variable upon another. It includes many techniques for modeling and analyzing several variables, when the focus is on the relationship between a dependent variable and one or more independent variables. More specifically, regression analysis helps one understand how the typical value of the dependent variable changes when any one of the independent variables is varied, while the other independent variables are held fixed. Most commonly, regression analysis estimates the conditional expectation of the dependent variable given the independent variables – that is, the average value of the dependent variable when the independent variables are fixed.

In present study, the regression analysis was done to find out an association of metabolic syndrome with energy and various nutrients, smoking, drinking and PAL.