PREVALANCE OF PREDIABETES IN URBAN SCHOOL GOING ADOLESCENTS AGED 11-17 YEARS WITH HIGH RISK FACTORS

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CERTIFICATE

This is to certify that the dissertation titled **"PREVALANCE OF PREDIABETES IN URBAN SCHOOL GOING ADOLESCENTS AGED 11-17 YEARS WITH HIGH RISK FACTORS"** submitted by **Dr. BALAMURUGAN.K,** to the Faculty of Pediatrics, The Tamil Nadu Dr. M.G.R. Medical University, Chennai in partial fulfillment of the requirement for the award of M.D. Degree (Pediatrics) is a bonafide research work carried out by him under our direct supervision and guidance.

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I **Dr.BALAMURUGAN.K,** solemnly declare that the dissertation titled **"PREVALANCE OF PREDIABETES IN URBAN SCHOOL GOING ADOLESCENTS AGED 11-17 YEARS WITH HIGH RISK FACTORS"** has been prepared by me.

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CONTENTS

INTRODUCTION

Obesity had become a major global epidemic in children. Last few decades have seen significant rise in the prevalence of overweight and obesity among children and adolescents of all countries. There is a strong association between all Non communicable diseases (NCDs) and Overweight and obesity. Today overweight and obesity and its consequences has become a major public health problem especially in urban areas in many developing countries, including India.

Type 2 diabetes mellitus (T2DM) is increasing at an alarming rate in adolescents and is becoming a public health problem throughout the world. The quality of life is affected because of it. Five to ten percent of all proven cases of diabetes are due to Type 1 diabetes mellitus (T1DM) and is the major cause of diabetes in children and adolescents. T2DM occurs mainly in adults who are overweight and older than 40 years. But now T2DM is occurring more often in young people because more children and adolescents all over the world had

become overweight, obese and sedentary. Below 10 years of age T2DM is rare irrespective of race or ethnicity.

The epidemic of T2DM in children and adolescents parallels the appearance of the obesity epidemic. This epidemic is also reported in India [1] and children of Indian origin in other countries.

The SEARCH study conducted in United States (US) children showed an highest incidence of type 2 diabetes among American Indian adolescents aged 15-19 years [2], followed by Asian-Pacific Islanders and black individuals of the similar age group. An increasing incidence of youth-onset T2DM during the recent past is also shown by studies among the Asian-American, Japanese, British, Indian, Taiwanese, Chinese, Libyan, Maori and Australian populations [1,3].

PRE-DIABETES:

Pre-diabetes is a condition that has been projected as a precursor to diabetes. It is a state of impaired glucose tolerance, or, impaired fasting glucose either singly or in combination.

The American Diabetes Association (ADA) criteria for diagnosis of pre-diabetes based on expert committee recommendations [4] are as follows:

- Fasting Plasma Glucose (FPG) between100 - 125 mg/dl (5.6 - 6.9 mmol/l) is called Impaired Fasting Glucose(IFG)
- 2-hour post-load glucose between 140 - 199 mg/dl (7.8 - 11.1mmol/l) is called Impaired Glucose Tolerance (IGT)
- HbA1c of 5.7 - 6.4%[4]

Those Patients with IFG and/or IGT are designated as 'pre-diabetes', recently reclassified as 'categories of increased risk for diabetes' by the ADA position statement 'standards of medical care in diabetes', released in 2010[4].The purpose of this is to erase the impression of 'inevitable progression to diabetes' associated with the term 'pre-diabetes' and to hope for reversibility to normoglycaemia. Hence, this group is an important target for vigorous intervention for primary prevention of diabetes.

EPIDEMIOLOGY:

The reported prevalence of pre-diabetes varies among populations with different ethnic background. 314 million people are currently affected with pre-diabetes all over the world, and it is likely that approximately 500 million people will have pre-diabetes by the year 2025 [5]. The current estimates are that up to 70% of pre-diabetic subjects eventually get diabetes.

CLINICAL SIGNIFICANCE:

The progression of pre-diabetes to T2DM has been studied in different populations with varying results.

- ✓ In general, approximately about 25% of subjects with Pre-diabetes progress to T2DM in 5 years, approximately 50% remain pre-diabetic and 25% revert to normal[6].
- ✓ In an 11 year follow-up study conducted in Mauritius, among adults with IGT , 46% developed diabetes, 28% remained pre-diabetic, and 26% reverted to normal. Those individuals with both IFG and IGT develop type 2 diabetes at approximately

two times more the rate than those who have a single abnormality[7].

- ✓ Diabetes progresses faster in children and is harder to treat than in adults.

THE INDIAN SCENARIO:

Indians including South Asians are at high risk for insulin resistance this is due to the presence of higher truncal fat in Indians than Caucasians[2].

The data regarding T2DM is minimal in Indian children and adolescents.

Ramachandran, *et al.* [2] clinic based study reported on 18children (13 girls and 5 boys) with T2DM diagnosed less than 15 years. Nine of them were obese. Of these 9 patients were without any symptoms and was detected on screening which was done due to strong family history of DM and/or due to obesity.

In the study by Bhatia, *et al.* [8] on children less than 18 years of age T2DM was recorded in 12% of cases out of 160 cases of diabetes mellitus.

An increase in prevalence of T2DM in children in our country, during the last ten years was also shown by other studies [9].

The Causative factors for this epidemic are

ENVIRONMENTAL AND LIFESTYLE-RELATED FACTORS (Urbanization):

- Due to improved standards of living, the micronutrient rich foods are replaced by energy dense highly processed foods.
- Increase in Sedentary pursuits.
- The heavy competition for admissions to schools and colleges, right from nursery levels with tuition classes forms an important factor for obesity.
- Many schools do not have playgrounds and children are forced to use their play time for additional studies.
- Children are not encouraged walking or cycling to school by parents due to unsafe roads for the fear of traffic and crime.
- Lack of parental supervision and decreased open spaces for exercise.

GENETIC FACTORS:

Thrifty Genotype and Thrifty Phenotype

Thrifty Genotype

These are the genes that conveyed a fast insulin trigger and thus the ability to store food rapidly as fat (savings), which become diabetogenic in modern setting of plentiful nutrition. This is also called as foetal origins hypothesis.

THE FOETAL ORIGINS OF ADULT DISEASE (FOAD) HYPOTHESIS:

Barker hypothesised that the associations between small size at birth or during infancy and later NCD`s reflect permanent effects of fetal under nutrition. The FOAD hypothesis proposes that although occurring in response to a transient phenomenon (foetal under nutrition) these adaptations become permanent or programmed because they occur during critical periods of early development.

Programmed changes may include reduced insulin sensitivity; low muscle mass, pancreatic beta cell mass and nephron numbers; altered arterial structure, and up-regulation of the HPA axis and sympathetic nervous system.

The FOAD hypothesis proposes that these changes also render the individual more susceptible to the effects of environmental stressors such as obesity arising in later life.

In India, the mean full term birth weight is 2.6 to 2.7 kg, almost 1 kg lower than in Western Europe. A world map of intrauterine growth retardation highlights South Asia as the worst affected region.

According to the FOAD hypothesis, increasing child and adult obesity in combination with persistently poor fetal growth creates a high risk for adult CVD and diabetes.

The time trends in CVD and type 2 diabetes in Western countries and in different socioeconomic groups during the 20th century, and the recent rise in developing countries, suggest a susceptibility to environment changes, which could either have genetic basis (thrifty genotype) or arise from fetal programming (thrifty phenotype).

Thrifty Phenotype:

The undernourished foetus develops insulin resistance and other metabolic changes as a strategy for immediate survival, to down-regulate and prioritize growth which later in life leads to problems like metabolic syndrome.

Both thrifty genes and the thrifty phenotype are detrimental on exposure to plentiful nutrition.

Foetal insulin hypothesis:

Since insulin is the major growth hormone in foetal life, genes associated with either insulin resistance or reduced insulin secretion would lead to reduced foetal growth as well as an increased risk of diabetes.

OTHER FACTORS:

Our carbohydrate based diet and a decline in rate of exclusive breastfeeding contributes to increased childhood T2DM in our population.

IMPORTANCE OF PRE-DIABETES IN INDIA

Diabetes related morbidity and mortality had become public healthcare issues in India due to increase in prevalence of pre-diabetes.

- ✓ Diabetes related micro-vascular complications can lead to blindness, kidney failure, and amputation. Its macro-vascular

complications are coronary artery disease, hypertension, cerebro-vascular accident.

- ✓ Impaired Glucose Tolerance (IGT) and Impaired Fasting Glucose (IFG) are also independently related with increased occurrence of cardiovascular events [10].
- ✓ The occurrence of diabetes in Indians is almost a decade earlier than in the western population [11]. Hence, most of the patients are from the economically productive age group. Moreover, the treatment cost of diabetes in an economically backward family may drain as much as 25% of the entire income for each person with diabetes. This information clearly dictates that clinicians must intervene at the pre-diabetic stage to prevent development of diabetes and a host of complications rather than ignoring pre-diabetes.

TYPE 2 DIABETES MELLITUS

Formerly known as adult-onset diabetes (or) non-insulin dependent diabetes (NIDDM) is a heterogeneous disorder, characterized by peripheral insulin resistance and pancreatic beta cell dysfunction.

It is considered as a polygenic disease aggravated by environmental factors, like decreased physical activity and excessive caloric intake. Asians are at risk for T2DM at lower degrees of total adiposity. Even though it is generally accepted that autoimmune destruction of pancreatic β cells does not occur in type 2 DM diabetes up to one third of the cases of adolescent type 2 DM may have autoimmune markers of type 1 diabetes like GAD65, ICA512 and IAA. The presence of these autoimmune markers does not rule out type 2 DM in children and adolescents.

Since hyperglycemia develops slowly, the affected individuals are usually asymptomatic for months to years or may present with mild symptoms like polyuria, nocturia and polydipsia. Typically they are obese. Type 2 DM has a stronger genetic component. Concordance rates among identical twins are in the 60-90% range.

The following are the high risk factors for T2DM in children [12]:

1. Overweight and Obesity.
2. Minority races (Native American, Hispanic, Black, Asian, and Pacific Islander).
3. Family history of type 2 diabetes.
4. Puberty (Relative insulin resistance peaks at this period).

5. Low birth weight.
6. History of gestational diabetes in mother.

SCREENING FOR TYPE2DM

- ✓ As children may be asymptomatic for prolonged period T2DM can remain undiagnosed.
- ✓ Type 2 diabetes related morbidity and mortality can be decreased by intense treatment in the pathogenesis stage itself.
- ✓ It is preventable, if managed in the pre-diabetes stage.
- ✓ American Diabetes Association (ADA) recommends opportunistic screening of at-risk asymptomatic children [13].
- ✓ Indians belong to a high ethnic risk group, so all overweight Indian children more 10 years in age with any one of the following risk factors should be screened for Type 2DM.

TESTING FOR TYPE 2 DIABETES IN CHILDREN WITHOUT SYMPTOMS :[14]

CRITERIA:

Overweight

WITH ANY 2 OF THE FOLLOWING RISK FACTORS:

- Family history of type 2 diabetes in 1st- or 2nd-degree relative
- Race/ethnicity (American Indian, African American, Hispanic, Asian / Pacific Islander)
- Insulin resistance signs or conditions associated with insulin resistance (acanthosis nigricans, hypertension, dyslipidemia, polycystic ovary syndrome)
- History of maternal diabetes or GDM during the child's gestation.

AGE OF INITIATION:

10 years or at onset of puberty (if puberty occurs at a younger age)

FREQUENCY:

Every 2 years.

TEST:

Fasting plasma glucose preferred.

PREVENTION:

1. Primary prevention:

The main step in primary prevention is lifestyle modification. These include the measures in the prevention of obesity and promotion of breast feeding.

2. Secondary prevention:

These are the ways to delay or prevent the emergence of complications of diabetes.

The main modes in secondary prevention are:

1. Good control of blood sugar.
2. Control of blood pressure.
3. Timely screening for long term morbidities.
4. Diabetes education.
5. Emotional and social support.

REVIEW OF LITERATURE

Overweight and Obesity:

Increasing numbers of children worldwide are estimated to be overweight or obese. According to International Obesity Task Force (IOTF) 2003 report, 1 out of 10 children in the age group 5 to 17 years are overweight or obese[15].

Obesity is defined as excess adipose tissue in the body. The most widely used indicator of obesity is the body mass index (BMI). It is a calculated by measuring a person's weight and height. Body mass index is defined as the weight (kg) divided by height (m^2).

BMI =WEIGHT (Kg) / HEIGHT

Body mass index is the preferred method for recognising the overweight or obese children. It is a less sensitive indicator of fatness in children as it is a measure of excess weight in relation to their height rather than excess body fat. Even though many approaches are present to measure body fat, most are unfeasible for practical use. The other important measure of adiposity is Waist circumference, but large

scale percentiles data in Indian children are not available at present. BMI has become the standard practical measure of adiposity. Even though there is no precise relationship between BMI and body fat content, an increased BMI is related to morbidity and mortality. BMI is now accepted as a standard method in children following its widespread use in adults [16].

According to WHO [30], Overweight is defined as > +1 Standard deviation (equivalent to BMI 25 kg/square meters at 19 years), while obesity is defined as >+2 Standard deviation (equivalent to BMI 30 kg/square meters).

At present, IAP has suggested to use WHO growth charts in which India was one of the participating countries in generation of these charts.

Biochemical changes in obesity:

Components of energy balance:

1. **Energy intake:**

   The calorie or energy content of the food varies from 4kcal per gram for carbohydrates to 9 kcal per gram for fat.

2. **Energy expenditure:**

   It is determined by the following 3 factors:

I. **Resting metabolic rate** (RMR):

It is the energy expended by the body to maintain normal physiologic functions. Resting metabolic rate occurs predominantly in muscles and other major organs. The resting metabolic rate for adolescence is 28 kcal / kg.

II. **Meal induced thermo genesis**:

It occurs over an extended period for at least five hours. The cumulative energy cost is equivalent to approximately ten percent of energy utilized. The thermogenic effect is higher for proteins (30%) and carbohydrates (15%) than for fat. This is because the process of energy storage is efficient for fat whereas additional

energy is required to convert carbohydrate and proteins to its appropriate storage form.

III. **Physical activity**:

The energy expenditure in physical activity is determined by the amount or duration of activity, type of activity and the intensity with which the activity is performed. The metabolic count of physical activity is expressed as metabolic equivalents or METS which represents multiples of resting metabolic rate. Sitting quietly after one hour fast is equivalent of one MET. The physical activity provides the greatest source of flexibility in the energy expenditure system and larger changes of energy expenditure can be achieved by physical activity.

The health professionals should advice to obese individuals about the calorific value of the food a person eats and the exercise which is necessary to burn off these calories. This is particularly useful in cases where the person is prone to snacking.

Examples of exercise types and the calorie and food equivalents:

Activity	Energy Expended Per Hour In Kcal	Food Equivalent Expended Per Hour
Driving a car	80	Slice of bread
Standing relaxed	100	Glass of wine
Standing doing light work	180	Bag of crisps
Walking five km per hour	260	One and half pints of beer
Walking seven km per hour	420	Two and half ounce peanuts
Running nine km per hour	600	Two chocolate bars

3. **Energy storage**:

When energy intake exceeds energy expenditure a state of positive energy balance occurs. An overfeeding relative to energy needs occurs; the body increases its overall energy source.

Epidemiology:

Obesity is a challenging public health problem and tracking of weight, height and BMI using simple charts. The factors that affect growth and development are interlinked and faced by several

confounding and modifying factors. The essence is that provide a nurturing environment during intra uterine and post natal life or rather starting from childhood and adolescent life of prospective mothers may act as a real preventive strategy against most adult onset diseases. At the same time it is important to tackle and control confounders, modifiers and amplifiers like feeding practices nutritional status and life style. it is better to pave the way for positive health, which is the motto of the era, rather than prevention.

1. Age:

Any age is susceptible but generally increases with age. Obesity in childhood is an important risk factor for obesity in adulthood and up to 80% of them become obese adults.

2. Sex:

Obesity was found in a higher rate in females than males and Overweight is more common in males.

3. Physical Inactivity:

Regular physical activity protects against unhealthy weight gain. Whereas sedentary life style particularly sedentary occupation, an inactive recreation such as watching television, video games and

computers which have replaced outdoor games. High burden of school work and academic competition have led to decreased participation in sports and other forms of physical activity. This is especially true for females who are sedentary from school life. Limited open space around home and the lack of appropriate play area makes it difficult for children to stay physically active.

4. Socioeconomic Status:

The direct relation to obesity to higher socioeconomic group is due to increased purchasing power, increased use of vehicular transport, sedentary lifestyle.

5. Eating Habits:

The etiology of obesity is dependent upon the diet composition, the periodicity with which it is eaten and energy derived from it. Eating habits established early in life are very difficult to change.

6. Socio Cultural Issues :

There is general misconception in India that an obese child is a healthy child and when a child is fat, the baby fat will go away with time.

ADOLESCENCE:

The now familiar term adolescence meaning to grow up was popularized less than hundred years ago. This is the period when child is transformed into an adult man or woman. It extends from onset of puberty till the time when sexual maturation is completed and encompasses physical, emotional, cognitive, social growth and developmental aspects bridging childhood and adulthood. Hormones, in conjunction with social structures designed to foster this transition, bringing about the change.

Depending on the purpose for which they are made, definitions vary as to the exact age range of adolescence and the physiological and psychological events that characterize it. In general WHO has defined it as a period from 10 to 19 years of age.

It has further been divided into three phases as early (10-13 years), middle (14-16 years) and late (17-19years) adolescence.

The term puberty is used to describe different phases of sexual maturation between childhood and adulthood, i.e. the time when procreation becomes possible. The term refers collectively to the

morphological, physiological and psychological changes occurring in the growing boys and girls, as the gonads change from the infantile to the adult state.

In this physiologic state of insulin resistance peaking at puberty, T2DM develops if inadequate beta-cell function is associated with risk factors [17]

FOOD HABITS:

The last two decades have witnessed tremendous changes in the food habits of Indian population, especially in urban and semi – urban areas. Just as there is changing in the trends of dietary pattern in general public, similar patterns are seen in children. Snacking is also very common. Fast foods appeal most to teenagers as it is inexpensive, well accepted and can be eaten informally without the use of utensils or plates. There is also decreased intake of whole milk and eggs, greater use of low fat and non - fat milk, more snacking and eating away from home among children and adolescents. Any negative impact of fast foods on the diet of adolescents depends on how frequently they are eaten and the choices made.

Factors influencing food intake in adolescence:

Food intake habits are determined by numerous factors. Major influences for children include the family, peers, media and body image.

1. **Family**:

Food habits and food likes and dislikes are formed in the early years and often continue into adulthood. Parents and siblings are the primary models for the young children to initiate the behavior. As children move into adolescents, they eat fewer meals at home.

2. **Media**:

Television is the primary media influence on children of all ages. One half of all commercials are for food, with even higher percentage found in children's programs. The food items generally advertised to young audiences are sweetened cereals, fast food, snack foods and candy foods high in sugar, fat and salt. The commercial messages are not based on nutrition but on emotional/ psychological appeal, i.e., fun, give you energy, yummy taste. Television viewing has been suggested as a factor in the rising rate of obesity among children and teen agers. In addition to encouraging inactivity, there is the steady presentation of food and eating cues.

3. **Peers**:

As children move into the world, their food choices are influenced by others. During school years, friends rather than the menu decide participation in the school lunch program. Peer influence is particularly strong in adolescence as teenagers strive more independence and eating becomes a more social activity outside the home.

4. **Body imag**e:

Puberty is the period of greatest awareness of body image. It is normal for teens to be uncomfortable and dissatisfied with their changing bodies. The media and popular idols offer a standard that adolescents compare themselves with, no matter how realistic it any be. To change their body image they may try restrictive diets, purchase weight loss products or in case of males, try supplements or diets in the hope of increasing their muscles. Some of these dietary measures may put them at risk for poor nutritional status.

Adolescents eating practices:

- Eating away from home
- Skipping meals
- Snacking
    - – Over 90% eat snacks
    - – Fast foods: These are high in fat, sugar and sodium
- Breakfast is the most common meal missed by adolescents
- Intake of more high energy low nutrient and low energy high nutrient food
- Interpretation of diverse feelings of situation as a reason to eat.

There is a strong association between obesity and type 2 diabetes in children and adolescents [2].

The following are the studies conducted in Tamil Nadu regarding the prevalence of overweight and obesity

- **Ramachandran,** *et al.* [3] studied children from 6 schools in Chennai, two each from high, middle, and lower income groups. The prevalence of overweight (including obese) adolescents ranged from 4.5% in lower income groups to 22% in higher income groups.
- **Shabana,** et al [(18)] found the overall prevalence of overweight to be 12.1% among the children and 15.5% among the adolescents in Chennai schools irrespective of socioeconomic status and gender.
- **Subramanyam,** et al.[(19)] showed the prevalence of overweight to be 9.6% and obesity 6.2% among well-off girls aged 10-15 years in Chennai in the year 1998.

Management of obesity:

1. Diet:

- Formal calorie-counting diets may be useful for getting someone who is obese or overweight started on a weight loss programme, but strict diets are difficult to sustain in a longer time. Most people like variety and enjoy treats. One of the most important aims in the programme is to help the patients to recognize danger foods particularly those high in fat, and help them to increase their own control over eating.
- Calorie counting and fat avoidance can be encouraged by asking the patient to keep a food diary which can also provide insight when weight loss is not proceeding as planned. The diet used should not prevent the patient enjoying normal social intercourse. Negative dieting is often counterproductive in the long term.
- The approach should emphasize new food opportunities, new methods of food preparation and the integration of treats into the overall food plan.
- The weight control programme is not just a one-off diet to give some rapid period of weight loss, but rather it is a process of re-education which will affect their whole life style. It is relatively

easy to lose weight over a short period, but more difficult to maintain that weight loss over a longer term. Only improved sight, changed dietary habits, behavioral change and exercise will sustain optimal weight.

The Atkins diet:

This is a high protein, low carbohydrate diet consisting of meat, cheese, etc, and avoiding starch, fruits, sugars and processed food.

Formula diet:

This is a balanced diet. This formula to eat meals for which 40% of the calories are derived from carbohydrates, 30% derived from proteins and 30% from fats.

The hay diet:

The hay diet is also known as ‘food combining for health’. It involves keeping starch foods separate from proteins in order to aid digestion.

Weight watchers pure points:

Each person attending weightwatchers weekly club session is privately weighed, and then there is a group discussion with the club leader to share news, hints and tips.

The pure point programme allots points rather than calories to a variety of food. Participants are allowed a predetermined number of points per day depending on how much they weigh and how much weight they need to lose. Most vegetables count zero points that means they can eat as much as they like. They can save points from daily allowance to put towards a special food treat. They can add up points by doing exercises.

2. Physical activity:

Specific recommendations for physical activity for people who are obese

- Slowly build up towards thirty minutes of moderate-intensity activity a day. The 30 minutes can be accumulated throughout a day in 10 – 15 minutes bouts.
- To achieve optimal weight loss, consider extending some sessions to 45 minutes or longer, as this will encourage the use of fat as an energy source.
- The duration of daily routine activity such as walking, gardening, house work, shopping etc., should be increased.
- Decrease the amount of time spent in sedentary activities.

- The most potent activities for weight loss are walking, swimming or cycling which involve large muscle groups.
- Consider weight-bearing exercises such as walking and climbing stairs, as these helps to maintain muscle mass and strength and resting metabolic rate (RMR).
- Find energetic activities which are enjoyable.

3. Behavioral therapy

Any behavioral approach should take into account the fact that eating is a highly reinforcing behavior. It induce feelings of gratification and pleasure which for some people is their main source of pleasure, and such individuals will not forsake their eating for pleasure habit very readily.

The five stages of change include the following:

1. Pre-contemplation
2. Contemplation
3. Preparation
4. Active change
5. Maintenance

Approaches to behavioral therapy are

- Self monitoring
- Stimulus control
- Coping with cravings
- Stress management
- Relaxation techniques
- Learn self control breaking the cycle between certain stimuli to eating particular foods and eating inappropriately
- Problem solving skills
- Mood management
- Manage work and family
- Relapse prevention
- Avoiding self defeating thinking
- Improving body image

4. Drug therapy

Most of the anti obesity drugs that have been used in the past have been withdrawn because they are ineffective or have adverse effects. Drugs should not be used as the only form of management – other components of therapy must continue. Stop drug therapy if weight loss is less than 5 % after first three months, or if there is weight gain at any period of time while he is on drugs.

5. Surgical therapy (bariatric surgery)

a. Restrictive procedures

b. gastric bye- pass

c. Jejuno – ileal bypass

d. Surgery for super-obese persons

e. Liposuction

f. Jaw wiring procedures

g. Apronectomy

h. Artificial bezoars

PREVENTION:

Prevention can be done by 2 approaches:

1. Universal approach:

The public health approach to obesity focuses on those elements of the social, cultural, political, physical, and structural environment which prevent a rise in the BMI of the population as a whole by

- Improving the quality of available diet.
- Promoting the level of physical activity and adopting healthy lifestyle
- Increasing the population knowledge regarding childhood obesity
- Involvement of community
- Monitoring and evaluation.

ROLE OF MEDICAL PROFESSION:

- The issue of obesity should be addressed during every child examination.
- Parents should be counseled to respect the child's appetite and not attempt to overfeed the child.

ROLE OF FAMILY:

- Food should not be used for non-nutritive purposes like for comfort or reward.
- Sugared foods should be avoided and healthy diet with ample fiber should be encouraged.
- Parents should restrict the amount of television viewing and encourage more physical activity, preferably by setting themselves as role models.

2. At Risk approach:

- This approach is directed at high-risk individuals who are at particularly high risk of obesity and its consequences.
- Selective prevention strategies should be initiated through schools, colleges and primary care, or through any appropriate setting, which allows access to high risk groups.
- The components of this approach are

    a. Prevention of weight gain.

    b. Promotion of weight maintenance.

    c. Management of health risks associated with obesity.

    d. Promotion of weight loss.

Family history of Diabetes:

There is a established evidence that 45-80% of children affected with diabetes are having at least one parent with diabetes and 74-100% of affected children are having a first or second degree relative with type 2 diabetes [(20).]

Acanthosis nigricans

It is a marker of insulin resistance. It is clinically characterized by a thickened, dark brown skin which is seen mostly on the back of the neck and in intertriginous areas. Studies show that it is noted in 90% of children with T2DM [[2].]

The following are the studies conducted in different countries regarding the prevalence of pre-diabetes

- **Babaoglu K,** et al[(21)] conducted a cross-sectional study between children aged 10-18 years in Kocaeli University, Turkey, showed prevalence of pre-diabetes to be 25.5% in obese children who also had a positive family history of DM2 and concluded that the problem of obesity and glucose intolerance was also present in developing countries. They also said that those obese children who had a positive family history of diabetes were at higher risk.

- **Chaoyang Li** et al.[22] estimated the prevalence of IFG, IGT, and pre-diabetes among U.S. adolescents aged 12–19 years to be 13.1%, 3.4%, and 16.1%, respectively and concluded that adolescents had a high prevalence of pre-diabetes.
- **Narayanappa** et al.[23] This school-based cross-sectional study showed the prevalence of pre-diabetes in Mysore city on 726 children aged between 5 to 10 years to be 3.7% using fasting blood sugar for screening and concluded that type 2 diabetes should be picked up in the asymptomatic pre-diabetes stage.
- **Sharma,** et al [24] conducted an analytic study in north India to compare the glucose tolerance among overweight and obese children with normal weight children as controls. Oral glucose tolerance test (OGTT) was used as a measure of glucose tolerance and showed that OGTT was impaired in four overweight adolescents and normal in all controls. In obese group, one obese child had fasting and 2 hourly blood glucose levels in diabetic range and OGTT was impaired in eight children. They concluded that overweight and obese adolescents should be monitored for abnormalities of glucose tolerance.

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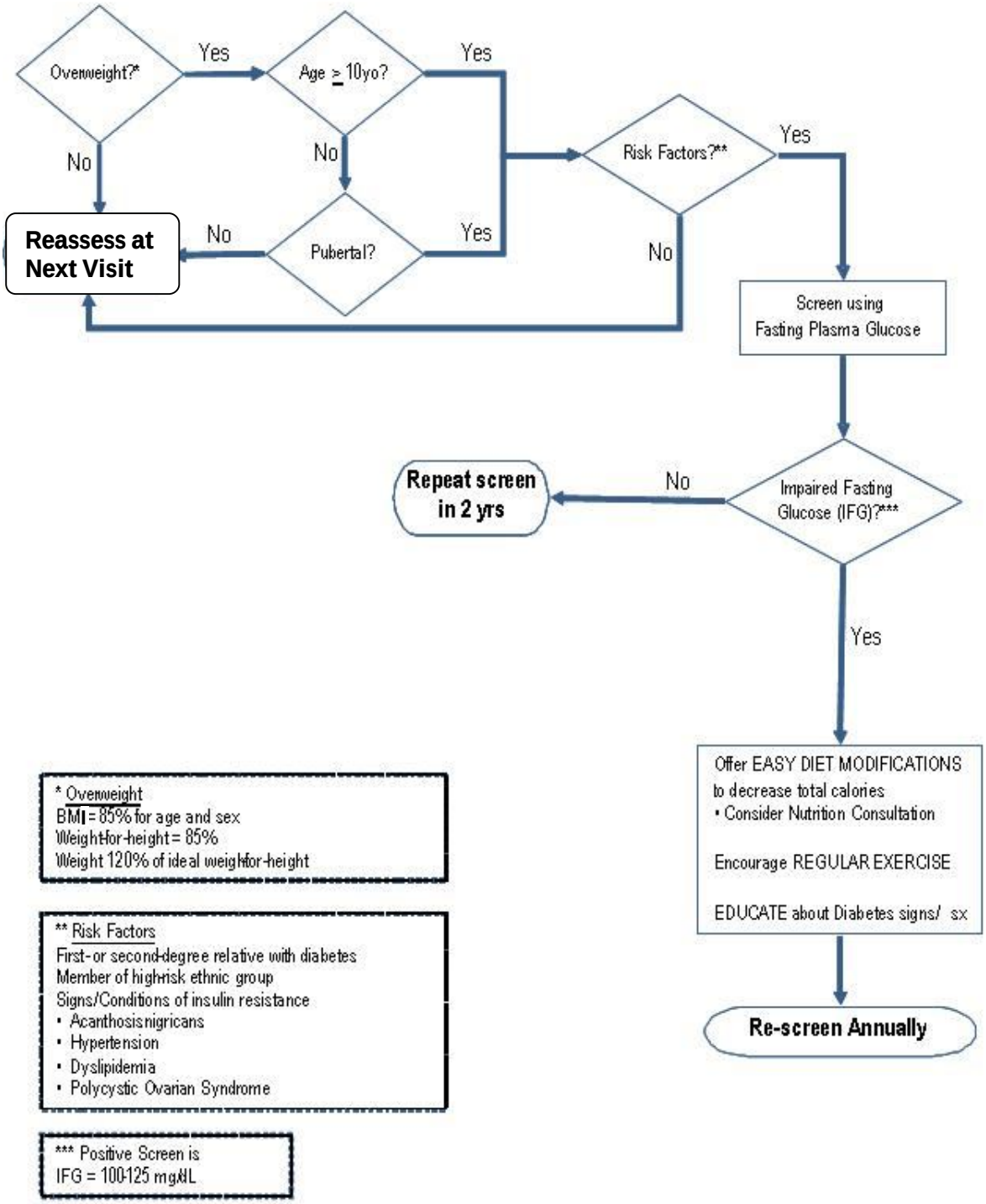
Management of pre-diabetes:

- ✓ The signs and symptoms of diabetes should be clearly explained to all pre-diabetic children and their families.
- ✓ Diet advice regarding low calorie, low fat should be given. Consultation with a dietitian is usually necessary.
- ✓ Implementation of regular exercise is advised.
- ✓ Pre-diabetic children should be under regular follow up and re-screened every year.
- ✓ High risk children should be re-screened with Fasting Plasma Glucose (FPG) every two years.
- ✓ For obese, insulin-resistant adolescents, Metformin may be useful and should be given to these patients by pediatric endocrinologists.

Screening and Management of Pre-Diabetes in Children



STUDY JUSTIFICATION

- ✓ Although population based prevalence data on type2DM in children are not available, existing information from clinic based studies shows that the prevalence of type 2 DM is increasing disproportionately among asian ethnic origin.
- ✓ As children may be asymptomatic for prolonged periods type 2DM in children may remain undiagnosed unless screened.
- ✓ Early diagnosis and preventive measures reduces the risks of micro & macro vascular complications.
- ✓ Forms a part of screening of high risk children as advised by American Diabetic Association (ADA).
- ✓ To start preventive measures early.
- ✓ Lifestyle modifications is the crucial aspect in the management of these children.
- ✓ Childhood provides an important opportunity to establish healthy eating and physical activity behavior as they are much more flexible than adults, to protect them against future obesity and its complications.
- ✓ Indian studies are lacking. No studies from our institution.

AIM OF THE STUDY

- To study the prevalence of Pre-diabetes in urban school going adolescents aged 11-17 years with high risk factors.

SUBJECTS AND METHODS

METHODOLOGY

Study design:

Cross sectional school based study.

Study population & place:

School children in the age group of 11-17 yrs at Chennai Corporation Middle, high, and higher secondary schools affiliated to ICH & HC school health cell who meet the inclusion criteria.

Study period:

December 2011 to November 2012.

Study population:

INCLUSION CRITERIA:

Adolescents aged 11 to 17yrs who are overweight (or) obese based on WHO Z-scores reference 2007 chart for boys & girls either with positive family history of diabetes (or) presence of acanthosis nigricans (or) both.

EXCLUSION CRITERIA:

1. Proven case of diabetes (Both T1DM and T2DM)
2. Children with chronic drug intake.
3. Children with chronic medical illness

CASE DEFINITION

1. Overweight

BMI >+1SD to <+2SD for age and sex

2. Obesity

BMI>+2SD to +3SD for age and sex.

The WHO Z-scores (2007) was used to classify children into overweight (or) obesity

3. Family history

Documented evidence of diabetes mellitus in parents, sibling, paternal and maternal grandparents, maternal and paternal aunty (or) uncle

4. Acanthosis Nigricans :

Characterized by dark, thick, velvety, pigmented skin in the neck.

Fig. Showing acanthosis nigricans in neck region

5. **Pre-diabetes:**

Defined as fasting plasma glucose value between 100mg/dl to 125 mg/dl.

6. **Sample size:**

148

ETHICS:

Ethical committee clearance was obtained from Institutional Review Board.

MANOEUVRE

- The schools affiliated to ICH&HC were selected by simple random sampling.
- Multiple sessions with school teachers and parents were conducted to explain about the study details.
- A pre-designed and pre tested questionnaire was used for eliciting detailed medical history and family history of diabetes, with parental help when necessary.
- Written informed consent was obtained from the parents or legal guardian and oral consent from the adolescents.
- Information regarding age was got from school records and was recorded in completed years.
- Initial screening of the adolescents aged 11 to 17 years by anthropometric measurement and physical examination.

ANTHROPOMETRY:

I. MEASUERMENT OF HEIGHT:

Height was recorded to the nearest 0.1cm using an in-built stadiometer. The height was measured with child standing in erect posture with heels, buttocks and back in close contact with the stadiometer. The head was positioned with child looking directly forwards so that the Frankfurt plane (the line joining floor of external auditory meatus to the lower margin of orbit) and the biauricular plane were horizontal.

II. MEASUREMENT OF WEIGHT:

Weight was taken using a balance-beam metric scale to the nearest 0.1kg, which was calibrated every day with a standard weight.

- The height and weight were taken after removing the footwear but no adjustments were made for the weight of shirt, pant, and underpants worn during the examination.
- BMI was calculated by the Quetlet Index

  BMI =WEIGHT (Kg) / HEIGHT (m^2)

- The subjects were classified into overweight (or) obesity using WHO Z-scores reference.
- The neck area is used to identify acanthosis nigricans in our study as it is easy to expose the neck area in practical settings and is more acceptable for the students. The neck area is found to be involved in 93 to 99% of the cases as evident from the previous studies [25].
- Fasting blood sugar was taken for those who are overweight (or) obese either with positive family history (or) presence of acanthosis nigricans (or) both, as recommended by ADA guidelines [26].
- After a minimum of eight hours fasting, venous blood samples were drawn and taken to lab immediately on cold chain conditions.
- Fasting plasma glucose measurement was used as the screening test for the diagnosis of pre-diabetes as it was convenient, easier and faster to perform, affordable, acceptable to adolescents and also recommended by the ADA guidelines. The oral glucose tolerance test although considered the 'gold standard,' was more costly and time consuming than the FPG test and was less reproducible

- ❖ Analysis was performed on venous samples for fasting plasma glucose by glucose oxidase - peroxidase method using fully automated analyzer.
- ❖ The parents were informed about fasting sugar values and those found to be pre-diabetic were given appropriate management.
- ❖ Fasting plasma glucose > 126 mg/dL was considered diabetes.
- ❖ Fasting plasma glucose < 100 mg/dL was considered normal [11].

STATISTICAL ANALYSIS:

- o The data entry was done in Microsoft Excel sheet.
- o Statistical analysis was done using SSPS software 17.0 versions.
- o Anthropometric measurements are given in mean and standard deviation
- o Descriptive analysis of study
- o The results were expressed as cross-tabulations and proportions.

OBSERVATION AND ANALYSIS

148 adolescents were enrolled in the study on the basis of inclusion and exclusion criteria.

Characteristics of study population

GENDER DISTRIBUTION

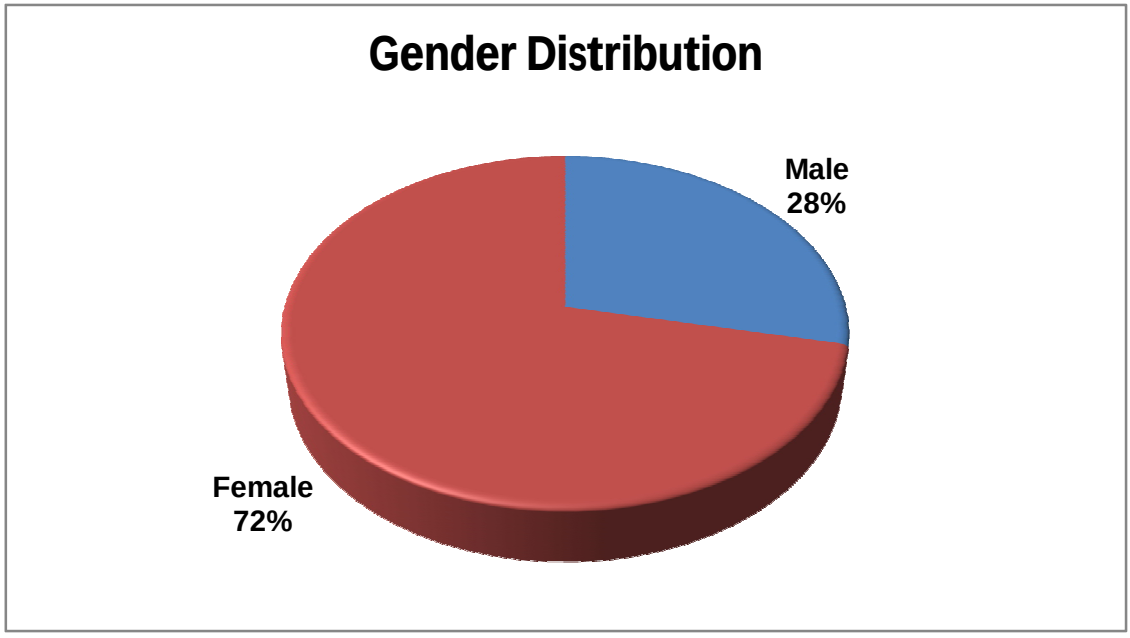


Figure No. 1

Among the 148 children in our study 42(28%) were males and 106(72%) were females.

AGE DISTRIBUTION

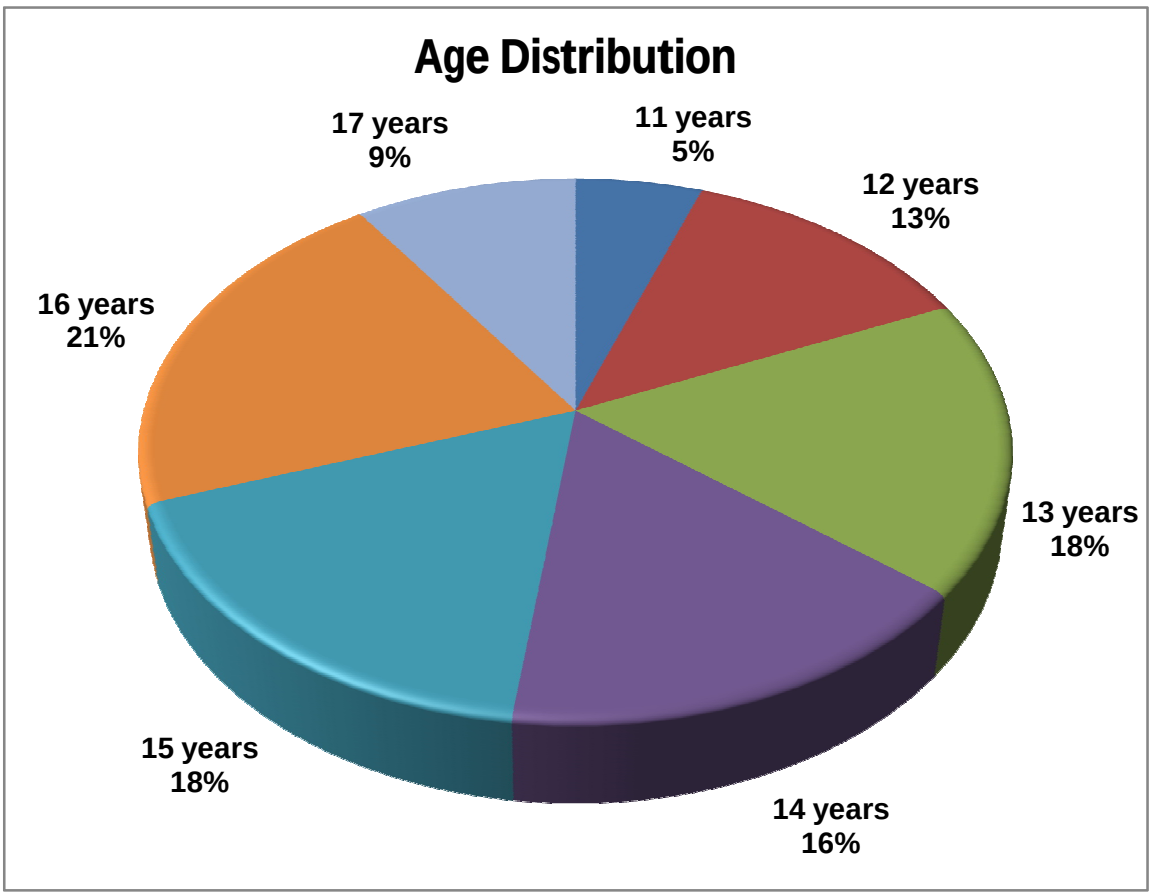


Figure No. 2

Among 148 children in our study 8 (5%) children belonged to 11 years, 19 (13%) children were 12 years, 26 (18%) were 13 years, 24(16%) children were 14 years, 26(18%) children were 15 years, 31(21%) children were 16 years, 14(9%) were 17 years. The age was given in completed years.

ANTHROPOMETRY

Anthropometric Data Regarding Weight for Age

	Age	No.	Mean	Std. Deviation	Minimum	Maximum
Wt (kg)	11	8	42.88	6.24	32.00	54.00
	12	19	53.05	9.06	38.00	74.00
	13	26	56.31	6.93	38.00	72.00
	14	24	59.17	10.24	45.00	89.00
	15	26	63.12	9.42	51.00	85.00
	16	31	65.10	6.81	54.00	81.00
	17	14	65.57	12.28	50.00	89.00
	Total	148	59.54	10.44	32.00	89.00

Table No. 1

Anthropometric Data Regarding Height for Age

	Age	No.	Mean	Std. Deviation	Minimum	Maximum
Ht (cm)	11	8	136.63	11.49	121.00	150.00
	12	19	147.95	4.89	136.00	153.00
	13	26	149.35	6.31	135.00	162.00
	14	24	150.67	7.48	135.00	168.00
	15	26	155.62	8.29	143.00	178.00
	16	31	152.90	6.11	142.00	165.00
	17	14	153.36	11.73	142.00	175.00
	Total	148	150.92	8.62	121.00	178.00

Table No. 2

Anthropometric Data Regarding BMI

	Age	No.	Mean	Std. Deviation	Minimum	Maximum
BMI	11	8	22.85	2.98	20.00	27.30
	12	19	24.55	3.58	20.90	33.00
	13	26	25.33	1.85	21.10	30.00
	14	24	25.89	3.12	22.00	34.00
	15	26	26.13	2.23	23.30	30.00
	16	31	28.16	3.23	22.00	34.00
	17	14	28.15	3.50	22.60	36.50
	Total	148	26.19	3.23	20.00	36.50

Table No. 3

ANTHROPEMETRY MEASUREMENTS (GENDER WISE)

	Gender	N	Mean	Std. Deviation	P-Value
Ht	Male	42	151.14	7.70	0.843
	Female	106	150.83	8.99	
Wt	Male	42	56.38	9.17	0.014
	Female	106	60.79	10.69	
BMI	Male	42	24.57	2.19	<0.001
	Female	106	26.83	3.363	

Table No.4

The mean height was found to be 151.14 cm for male and 150.83 cm for female. The difference did not achieve statistical significance (p=0.843). The mean weight of male adolescent included in the study was 56.38 kg and the female was 60.79 kg, which was statistically significant difference (p=0.014). There was found to be a statistically significant difference in the body mass index between the genders (p<0.001) with a mean of 26.83 for female and 24.57 for male adolescents. The anthropometric measurements were found to be higher in female children in all age groups.

DISTRIBUTION OF OVERWEIGHT AND OBESITY IN STUDY POULATION

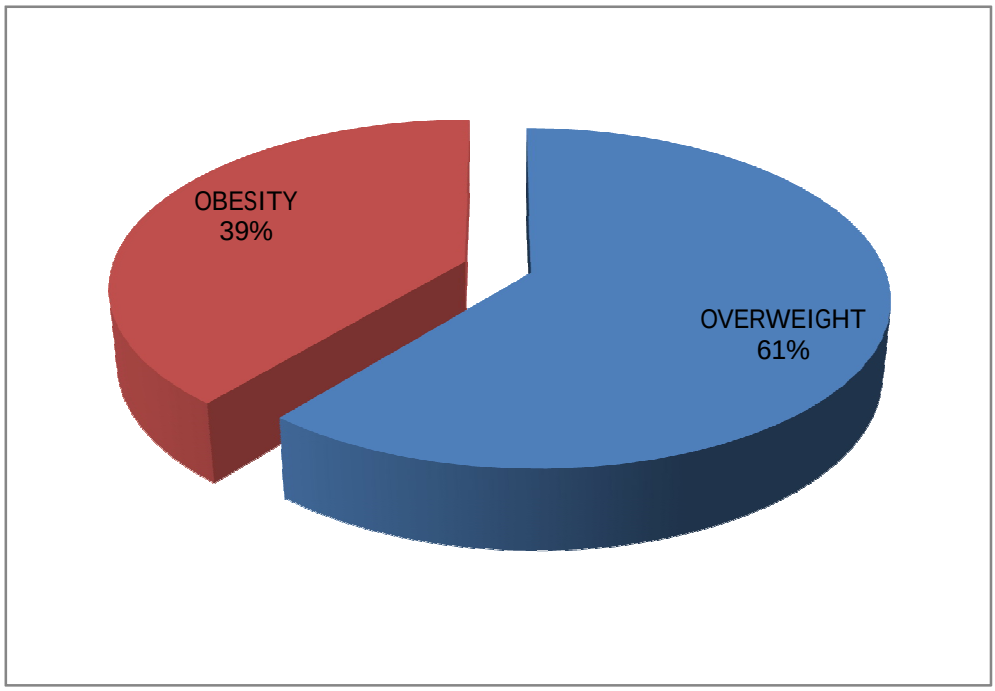


Figure No.3

Among the 148 adolescents, 90 (61%) were overweight and 58 (39%) were obese for their age and gender.

DISTRIBUTION OF ACANTHOSIS NIGRICANS IN STUDY POPULATION

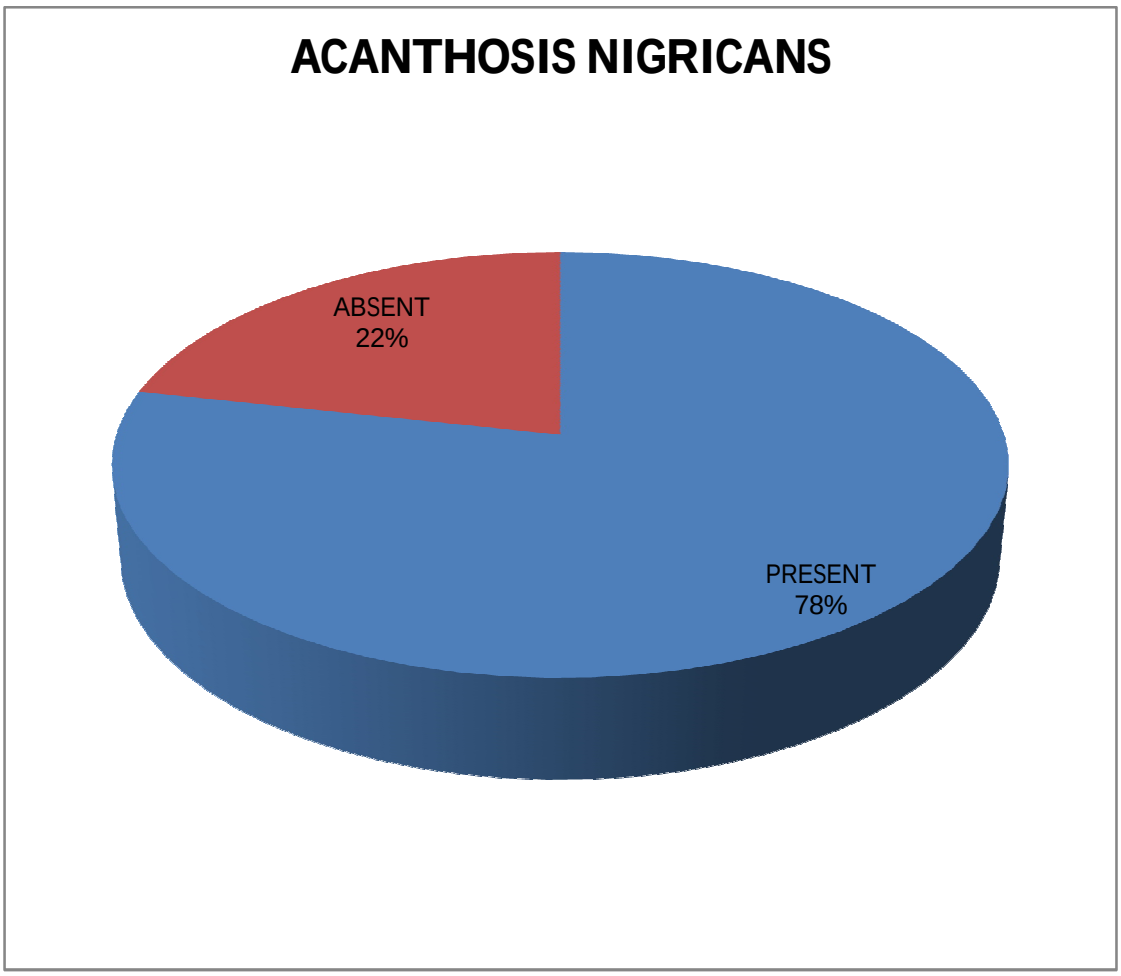


Figure No.4

Among the 148 adolescents 116 (78%) had acanthosis nigricans and 32 (22%) had no acanthosis nigricans.

DISTRIBUTION OF FAMILY HISTORY OF DIABETES

IN STUDY POPULATION

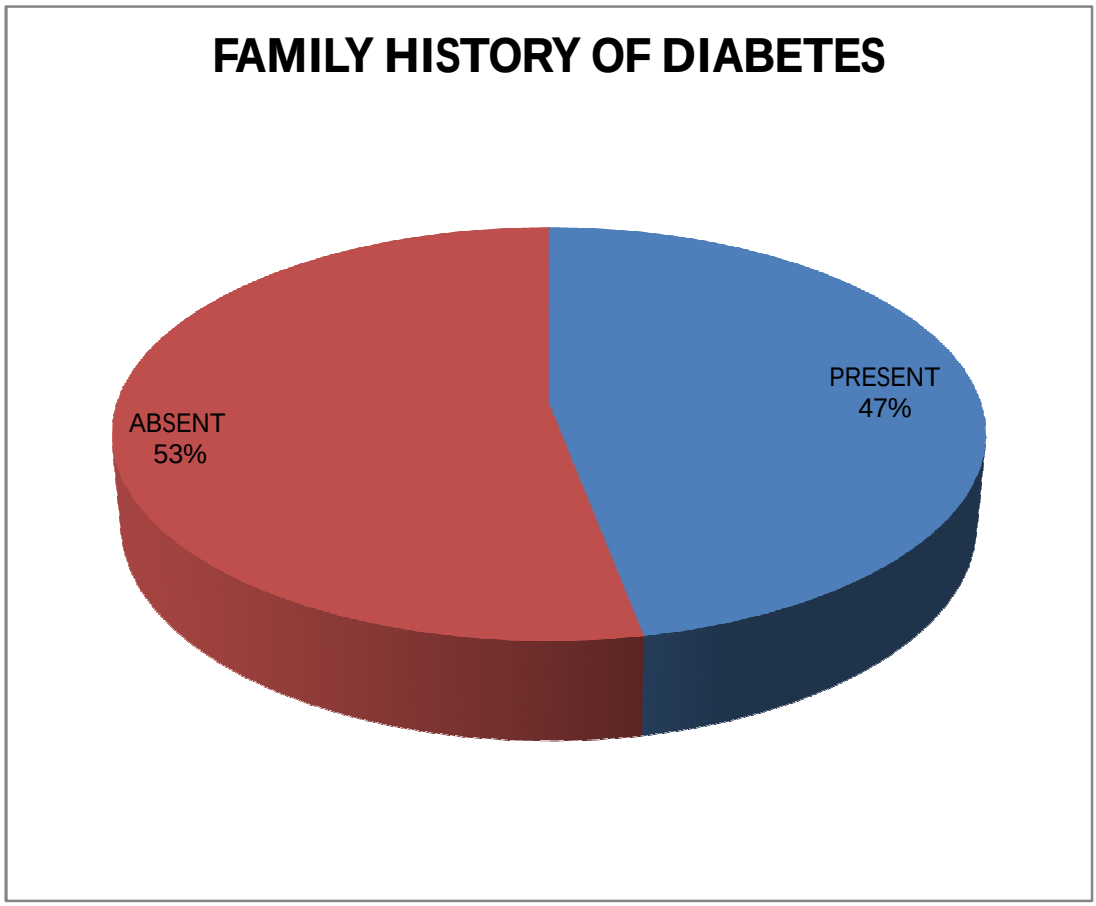


Figure No.5

Family history of diabetes mellitus was present in 70(47%) overweight and obese adolescents whereas it was absent in 78 (53%) of them.

PREVALANCE OF PREDIABETES

Gender	Pre-diabetes	
	No	Yes
Male	38(90.5)	4(9.5)
Female	92(86.8)	14(13.2)
Total	130(87.8)	18(12.2)

Table No.5

Values in parentheses are percentages

In our study the prevalence of pre-diabetes was 12.2%.

PREVALANCE OF PREDIABETES-GENDERWISE

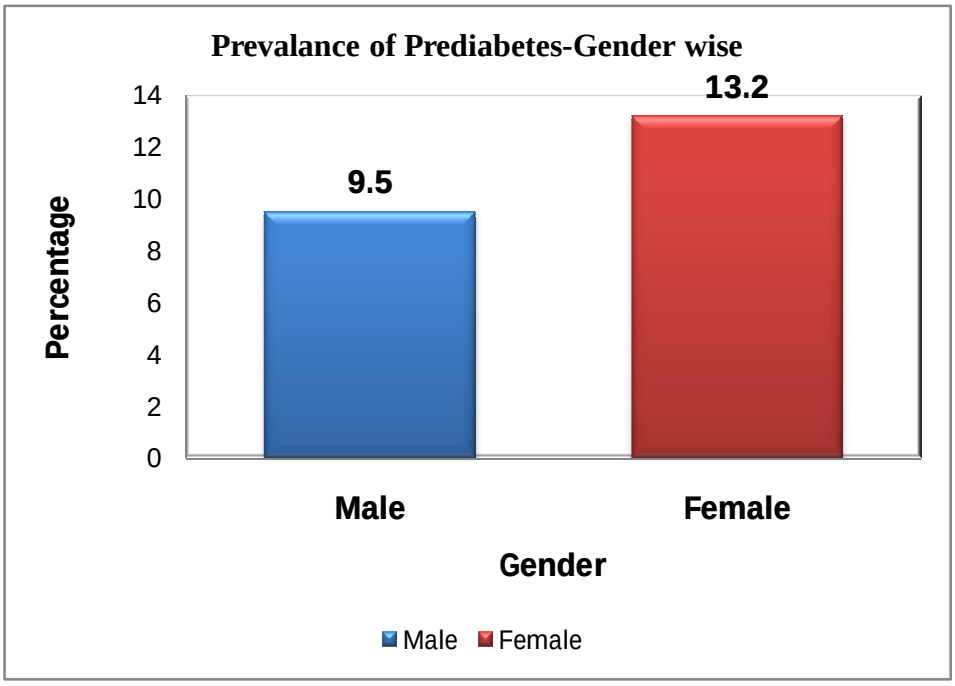


Figure No. 6

It was 9.5% in males and 13.2% in females.

AGEWISE PREVALENCE OF PRE-DIABETES

Age (yrs)	Pre-diabetes	
	No	**Yes**
11	7(87.5)	1(12.5)
12	17(89.5)	2(10.5)
13	21(80.8)	5(19.2)
14	21(87.5)	3(12.5)
15	25(96.2)	1(3.8)
16	27(87.1)	4(12.9)
17	12(85.7)	2(14.3)
Total	**130(87.8)**	**18(12.2)**

Table No.6

Values in parentheses are percentages

Figure showing the age-wise prevalence of pre-diabetes

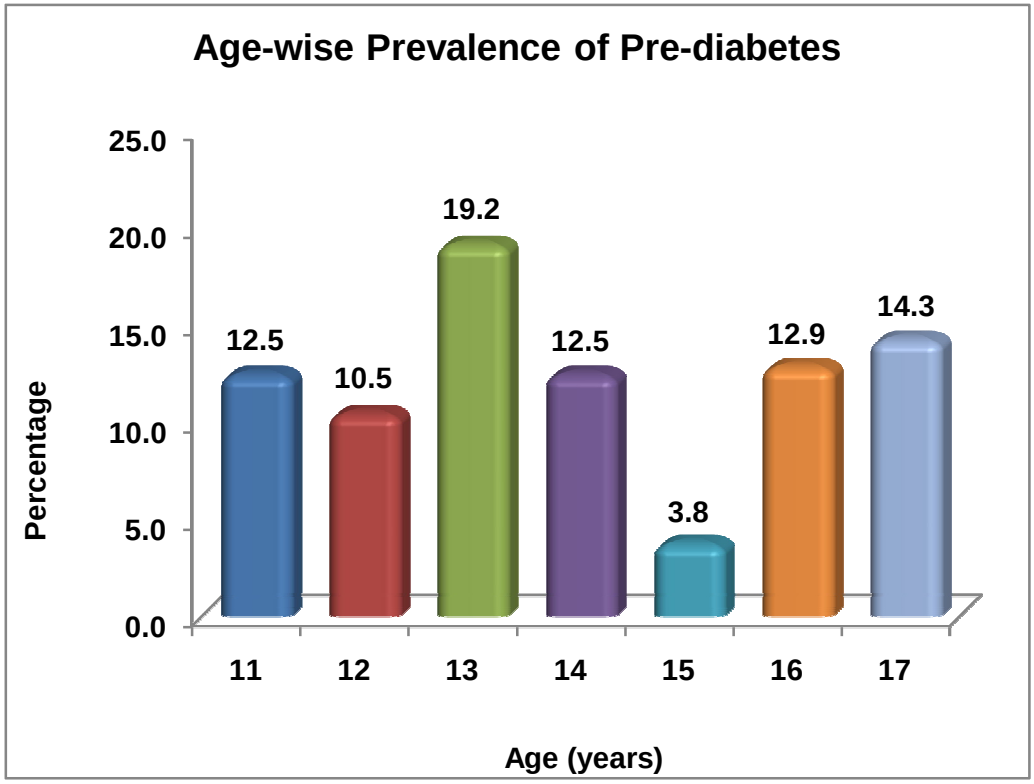


Figure No.7

Prevalence of pre-diabetes peaks around 13 years and starts in a rising trend as age advances. It peaks at 13 years at the time when physiological pubertal peak occurs.

PREVALENCE OF PRE-DIABETES AMONG FAMILY HISTORY OF DIABETES:

Family History of diabetes	Pre-diabetes	
	No	**Yes**
Nil	76(97.4)	2(2.6)
Parents	23(69.7)	10(30.3)
Grand parents	19(86.4)	3(13.6)
Others(maternal and paternal uncle or aunty)	12(80)	3(20)
Total	**130(87.8)**	**18(12.2)**

Table No.7

Values in parentheses are percentages

This table shows that prevalence of pre-diabetes was more in those with history of diabetes in parents.

It also shows that 16 (89%) pre-diabetics had positive family history of diabetes while 2 (11%) pre-diabetics had no family history of diabetes.

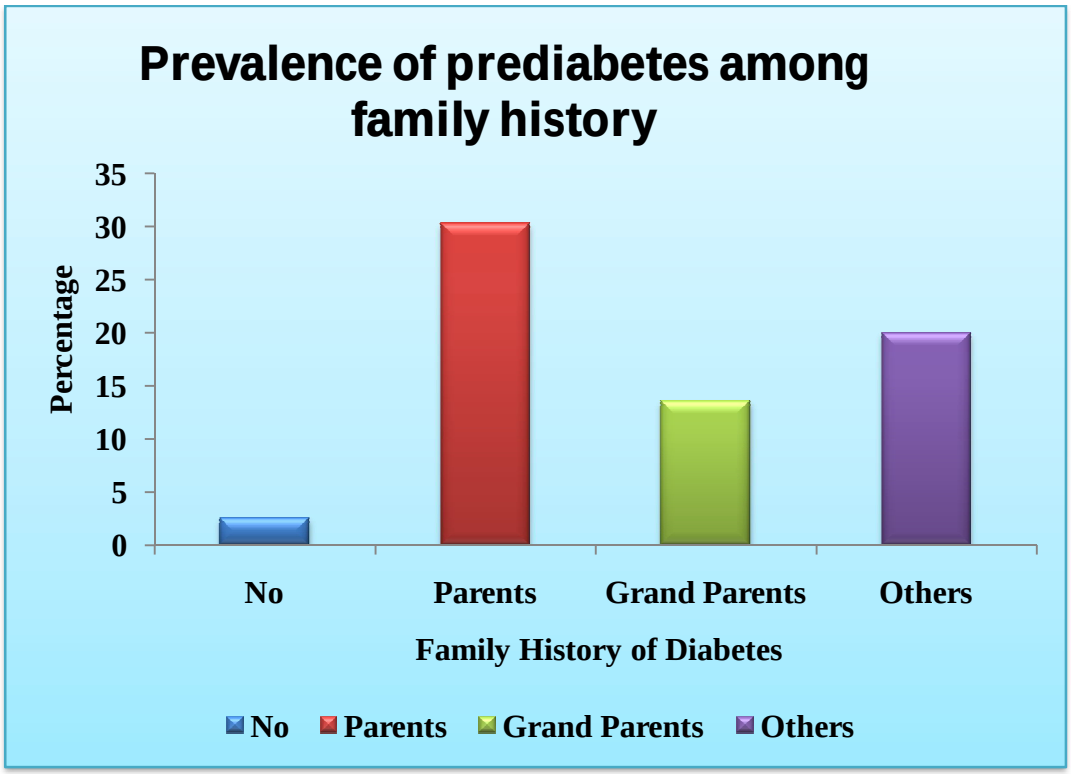


Figure No.8

Fig. Showing the prevalence of pre-diabetes in relation with positive family history of diabetes.

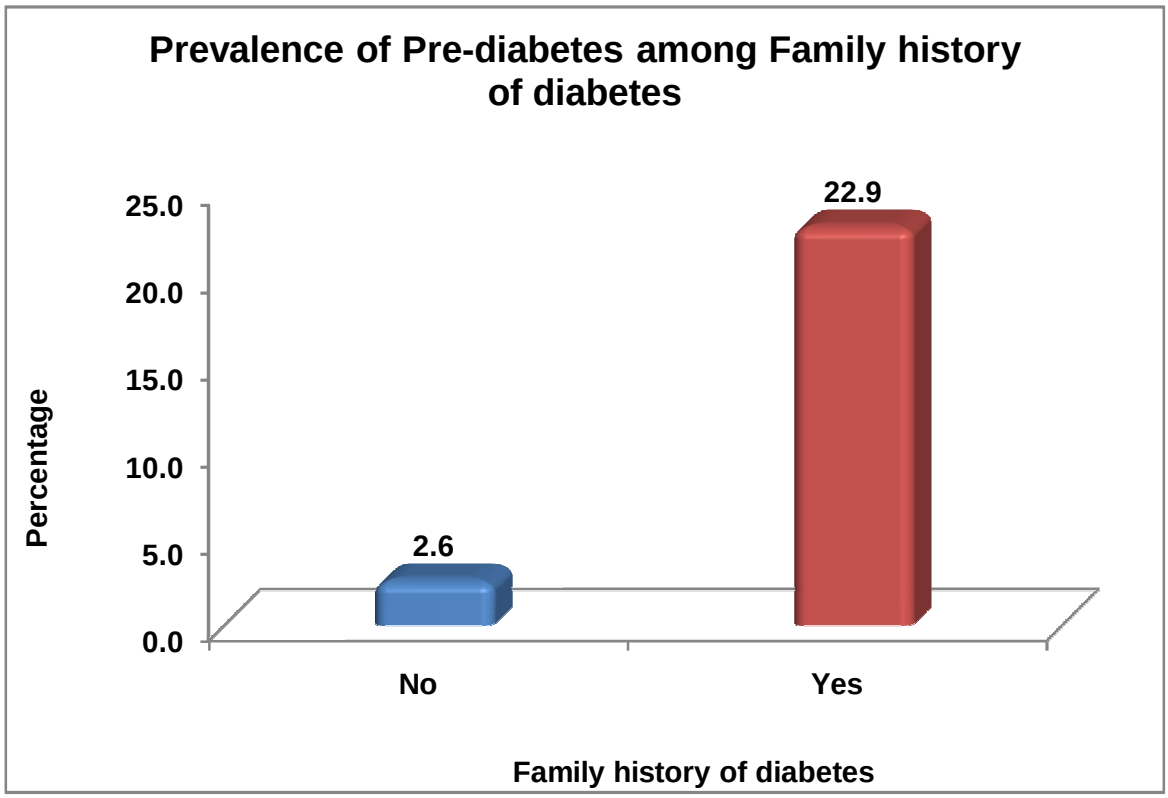


Figure No.9

Pre-diabetes was nearly 23 times more prevalent in those with positive family history which was statistically significant ($p<0.001$)

PREVALENCE OF PRE-DIABETES AMONG

OVERWEIGHT AND OBESITY

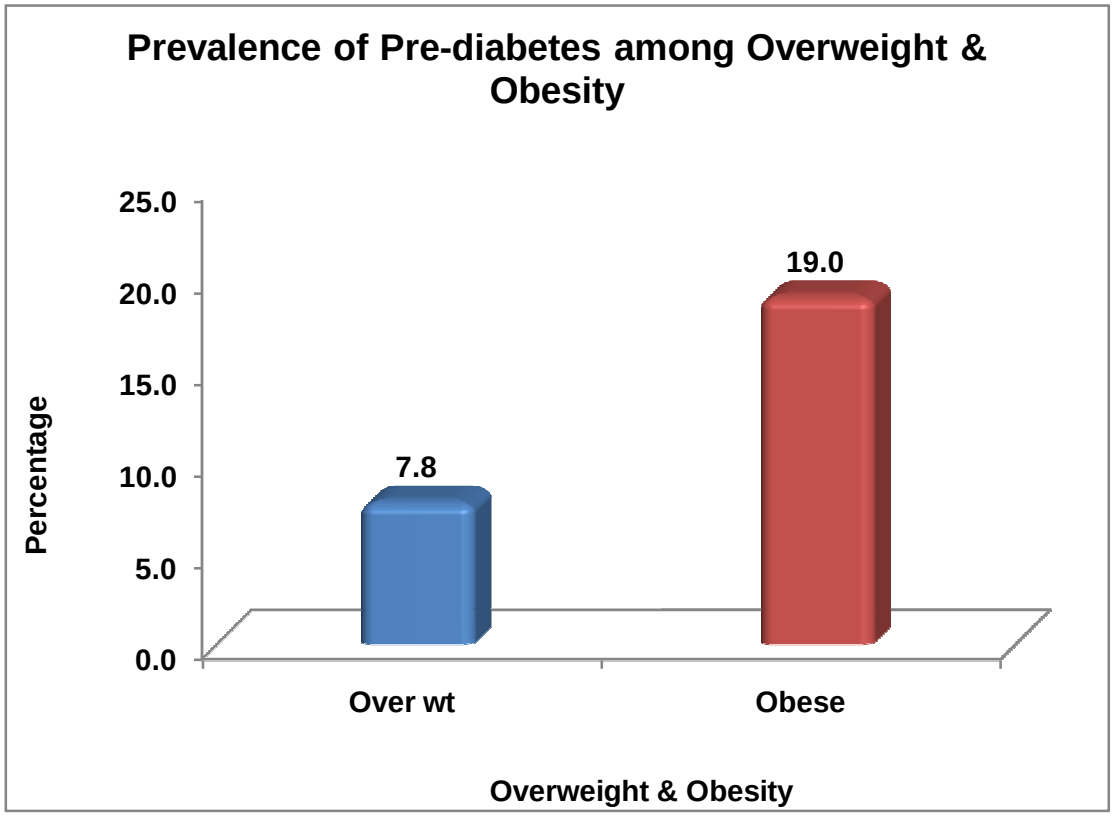


Figure No.10

Pre-diabetes was more prevalent in obese individuals.

PREVALENCE OF PRE-DIABETES AMONG THOSE WITH ACANTHOSIS NIGRICANS:

Acanthosis Nigricans	Pre-diabetes	
	No	Yes
No	29(90.6)	3(9.4)
Yes	101(87.1)	15(12.9)
Total	130(87.8)	18(12.2)

Table No.8

Values in parentheses are percentages

The prevalence of pre-diabetes among Acanthosis Nigricans was 12.9%.

Acanthosis nigricans was present in 15 (83%) pre-diabetics while it was absent in 3 (17%) pre-diabetics.

Fig. showing the prevalence of pre-diabetes among Acanthosis Nigricans:

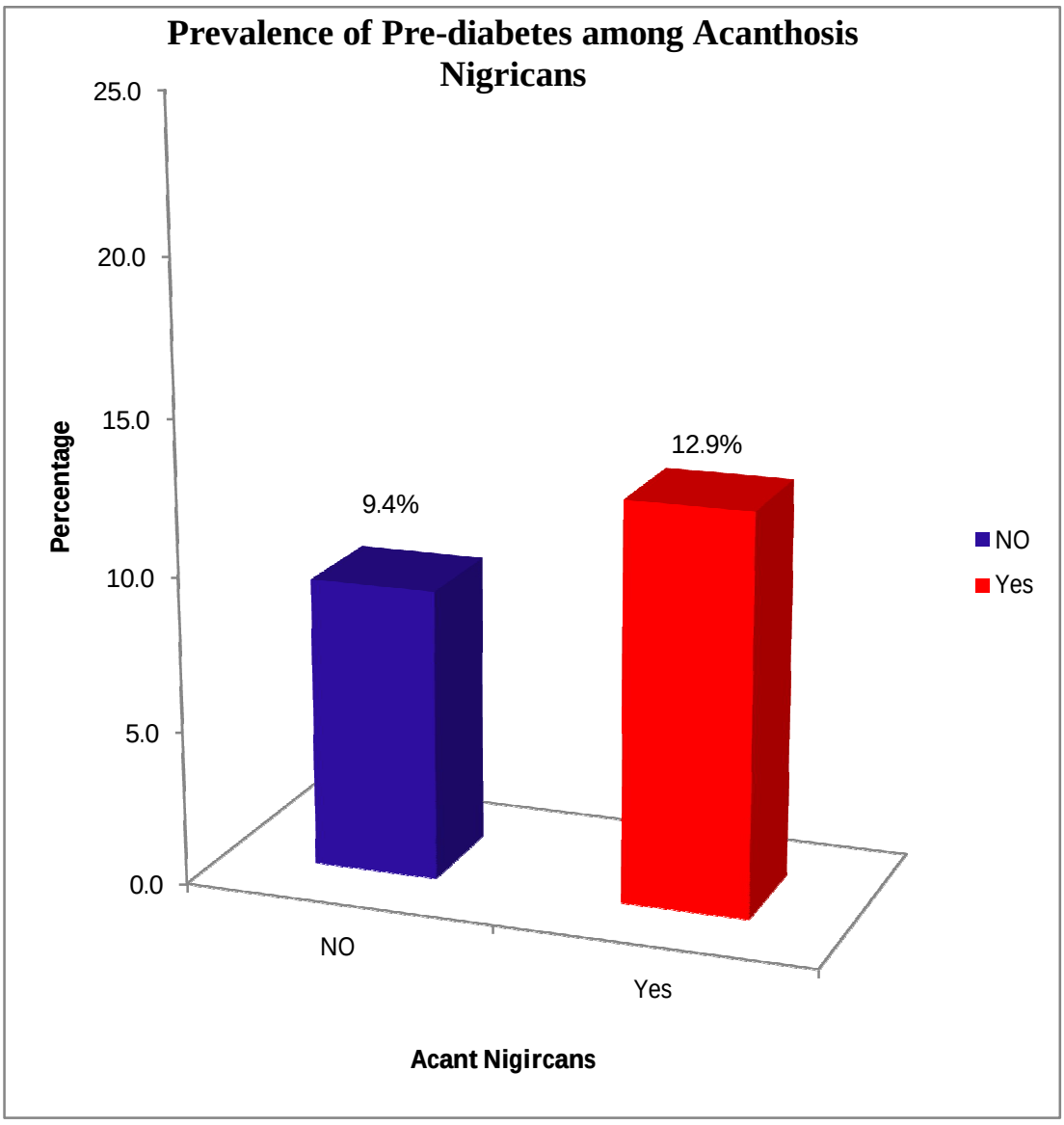


Figure No.11

ANALYSIS OF BLOOD SUGAR VALUE

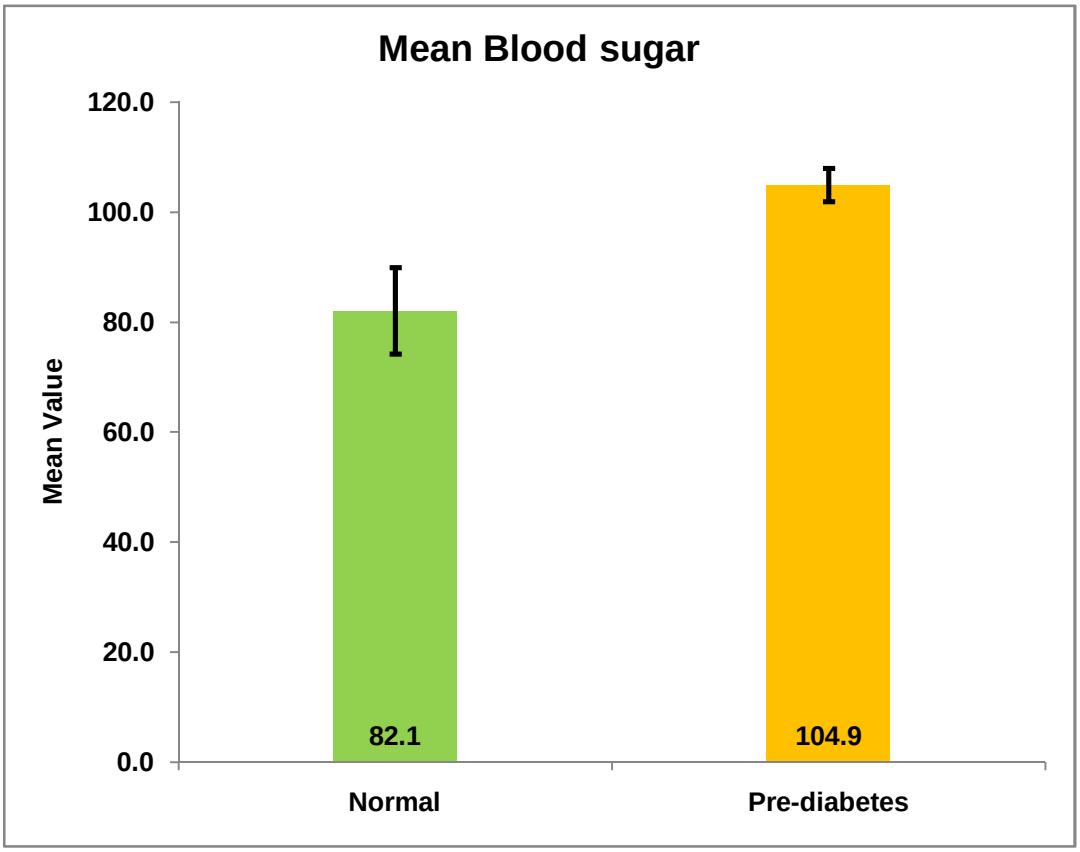


Figure No.12

The mean blood sugar value of overweight and obese individuals who were normal was 82.1, while those who were pre-diabetic was 104.9.

DISCUSSION

According to International Diabetes Federation (IDF) around 40.9 million diabetes patients are in India and this may further rise to 69.9 million by the year 2025 [11]. Comparing to Western population T2DM develops at a decade or two earlier in Indians (1).

Schools were chosen for conducting the study because if children were educated about the need to practice a healthy diet and exercise routine in their schools, they most probably tend to make healthier choices and can prevent the progression of pre-diabetes to diabetes. Schools have been recognized as the perfect spaces to administer intervention strategies because of their impact on the family and society.

Anthropometry:

148 overweight/obese children were included in this study. The body weight and body mass index were found to be higher in female gender than male in this in all age group. This finding was in concordance to that reported from other studies done by Subramanian,

et al [19] and Shabana, et al [18], which reported higher prevalence of obesity/overweight in female gender. Females have a greater preponderance to been overweight compared to males owing to their inherent hormonal differences.

In our study 12.2% of adolescents with high risk factors had pre-diabetes. Studies done in adolescents aged 11-17 years with high risk factors were minimal to compare the data from this study. The National Urban Diabetes Survey done in adults above 20 years, showed the prevalence of impaired glucose tolerance to be 8.6% in New Delhi, 16.8% in Chennai, 10.8% in Mumbai, 14.8% in Bengaluru, 10% in Kolkatta, 29.8% in Hydrabad [11]. Impaired fasting glucose or impaired glucose tolerance was present in 11.2% of the subjects in the Amrita Diabetes and Endocrine Population Survey done in Kerala [11].

Publications regarding the natural history of type 2 diabetes in children are minimal. Similar to adults, children also have an asymptomatic phase during which the disease can be diagnosed [27]. While the duration of diabetes prior to clinical diagnosis has been

estimated as 4-7 years in adults this has not been estimated in children[27].

Overweight and obesity, positive family history influences the progression of pre-diabetes. Studies done in patients with impaired fasting glucose had shown that lifestyle modification and treatment with pharmacological agents like metformin can prevent the onset of diabetes [27]. It has been shown in many studies that pre-diabetic states are high risk stages for cardiovascular disease [11].

In the recent study conducted by Ranjani et al [31] among the children in general population aged 12 to 19 years in Chennai showed that 4.2% of girls were pre-diabetics and 3.2% of boys were pre-diabetics. The overall prevalence of pre-diabetes was 3.7%. In our study the prevalence of pre-diabetes among the girls with high risk factors was 13.2% and in boys was 9.5%. This clearly reveals that girls with high risk factors have nine times more chance of getting pre-diabetes than those in general population and boys have nearly six times more risk. The overall prevalence in our study was 12.2% which was nearly more than eight times in general population. These findings indicates the need to identify high risk persons by simple

screening methods and institution of lifestyle modification methods to prevent diabetes.

Family history of diabetes was present in 89% of adolescents with pre-diabetes which is similar to the established evidence that nearly 80% of children affected with diabetes are having positive family history of diabetes [20].

In a study conducted by Michael et.al [28] impaired glucose tolerance was found in 28% of obese Hispanic children with positive family history of type 2 diabetes and no case of type 2 diabetes. In our study also no case of diabetes was found but the prevalence of pre-diabetes was found to be 12.2% and this can be explained by racial differences in study group and the methodology used to define pre-diabetes.

In our study 13.2% of the females and 9.5% of the males were pre-diabetic. This difference may be due to the hormonal changes which are more rapid in females than males.

In a study conducted in New Delhi by Kaur et al [29] 18.2% of obese children had pre-diabetes (impaired glucose tolerance). In our study also 19% of obese children had pre-diabetes.

In our study the prevalence of pre-diabetes among those with positive family history of diabetes was nearly 23 percent, while in a study conducted by Chaoyang et al in U.S. Adolescents it was 25 percent[22].

In our study Acanthosis nigricans was present in 83% of adolescents with pre-diabetes, while it was present in 90% of children with T2DM [2].

The difficulties in achieving good blood sugar control and preventing diabetes related complications after the diagnosis of diabetes, which is more common in high risk population like overweight & obesity makes us to diagnose diabetes in the pre-diabetic stage itself to implement preventive strategies to halt the progression of pre-diabetes to diabetes.

Also we would propose to conduct nationwide study to detect pre-diabetes in high risk population and the implementation of Lifestyle intervention measures to reduce the incidence of diabetes in our country and save the future Pillars of our Nation.

CONCLUSIONS

- ✓ Targeted screening of high risk children for pre-diabetes is justified.
- ✓ Recognition type 2 diabetes in the asymptomatic pre-diabetes state must be emphasized.
- ✓ The morbidity and mortality due to youth onset type 2 diabetes can be reduced only by early detection and treatment.

LIMITATIONS

Our study analyzed only the prevalence of pre-diabetes in adolescents with high risk factors. The sample size was small to make comparisons and to draw conclusions for the general population.

Large scale studies are needed to know the prevalence of pre-diabetes in adolescents among general population.

RECOMMENDATIONS

- ✓ High-risk children in the general population should be screened who can be picked up by - presence of overweight or obesity along with any one of the following risk factors like positive family history of diabetes or acanthosis nigricans.

- ✓ The general public, general physicians, pediatricians, schools and teachers, the government and professional medical bodies, the media should be involved to create awareness for prevention of T2DM in the young population of India by screening them in asymptomatic pre-diabetic state and this can be achieved only by a concreted and multipronged effort.

- ✓ Daily physical activity/sports for all children and physical fitness programs in the school should be made compulsory.

- ✓ Appropriate screening programs should be initiated for high risk children in schools.

- ✓ Lifestyle modification should be encouraged and implemented at school level.

- ✓ Regular follow up and constant motivation is must for preventing the progression of pre-diabetes.

- ✓ Framing an appropriate national guideline/program for detection of pre-diabetes in high risk children.

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ABBREVATION

ADA	-	American Diabetes association
FOAD	-	Foetal Origin of Adult Diseases.
T2DM	-	Type 2 Diabetes Mellitus
T1DM	-	Type 1 Diabetes Mellitus
BMI	-	Body Mass Index
FPG	-	Fasting Plasma Glucose
GAD	-	Glutamate Decarboxylase
ICA	-	Islet Cell Antibody
IAA	-	Insulin Auto Antibody
IFG	-	Impaired Fasting Glucose
IGT	-	Impaired Glucose Tolerance
IDF	-	International Diabetes Federation
NIDDM	-	Non-Insulin Dependent Diabetes Mellitus
RMR	-	Resting Metabolic Rate
IAP	-	Indian Academy of Pediatrics
ICH & HC	-	Institute of child Health & Hospital for children
IOTF	-	International Obesity Task Force
NCD	-	Non Communicable Disease
OGTT	-	Oral Glucose Tolerance Test
WHO	-	World Health Organization

PROFORMA FOR THE STUDY:

ID No:

NAME:

AGE:

SEX:

SCHOOL: Middle/High/Higher Sec.

Standard :

Residential Address & Phone no.

MEDICAL HISTORY:

FAMILY HISTORY OF DIABETES: Mother/Father/1st degree relative/2nd degree relative

If present, age of onset.

Physical Examination:

HEIGHT (cm) :

WEIGHT (kg) :

BMI:

Vitals:

Systemic Examination:

ACANTHOSIS NIGRICANS: Present/Absent

Assessment:

Normal weight / overweight / obese

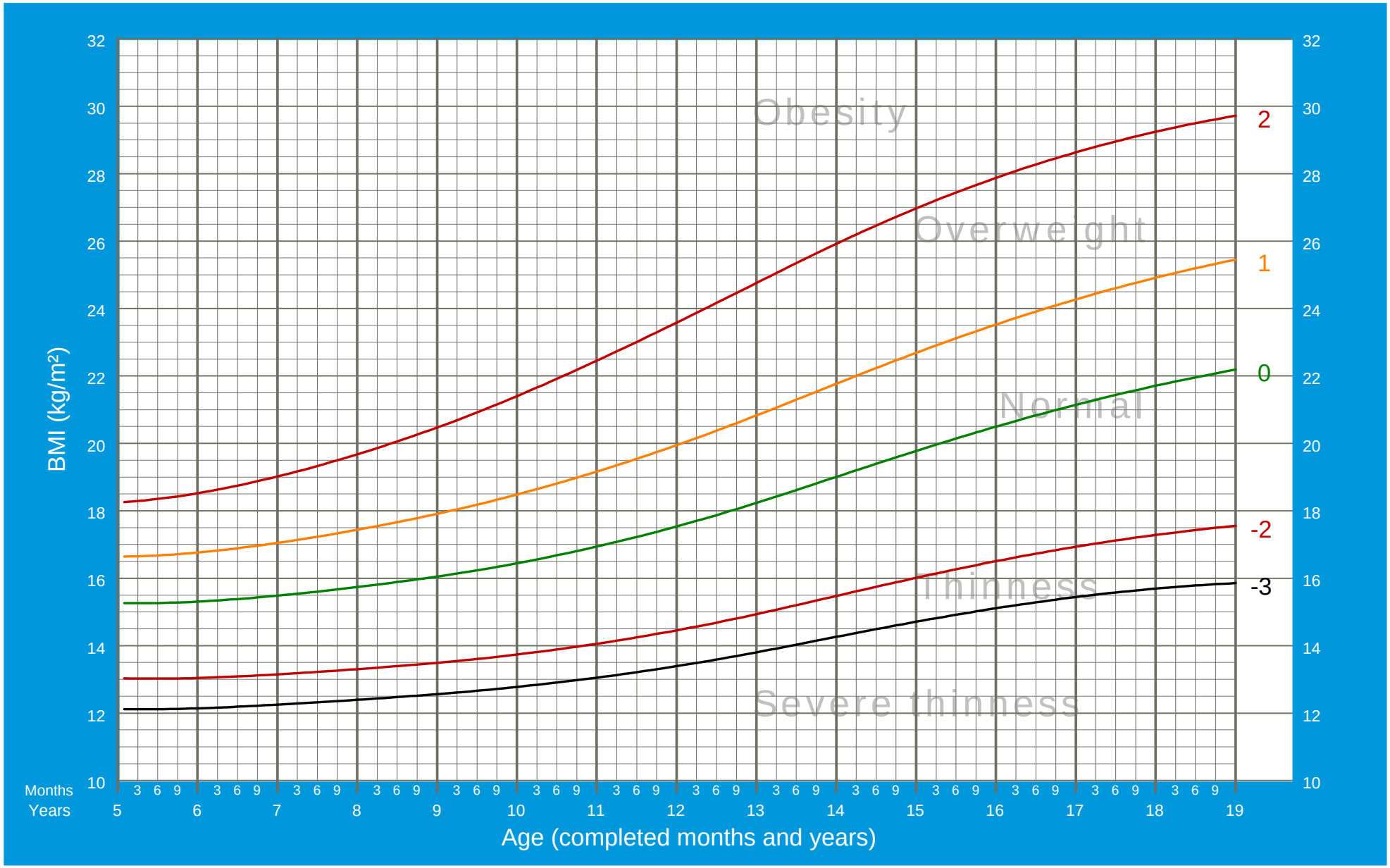
Fasting Plasma Glucose

Normal / pre-diabetes / diabetes

BMI-for-age BOYS

5 to 19 years (z-scores)

World Health Organization



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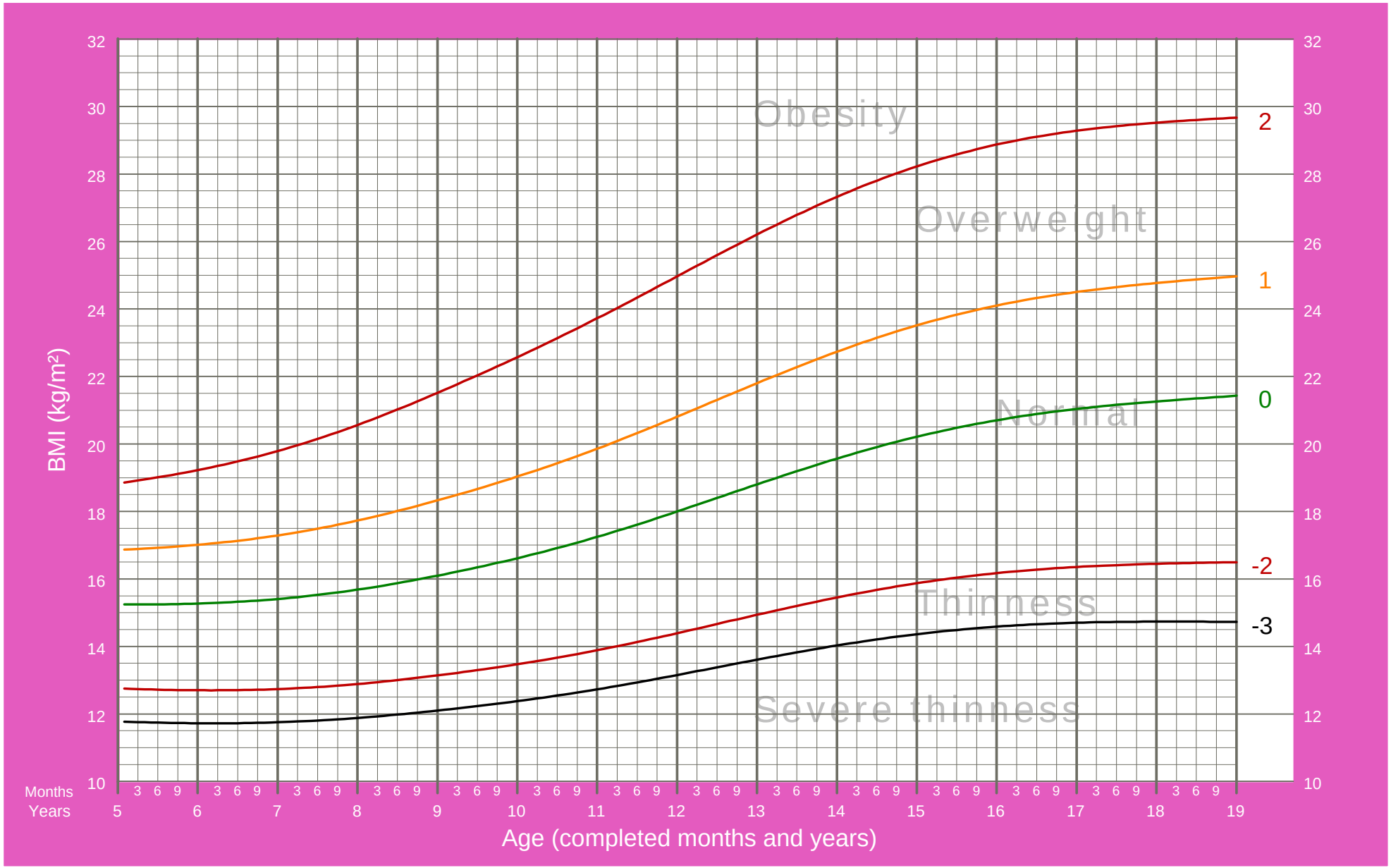
BMI-for-age GIRLS

5 to 19 years (z-scores)

World Health Organization



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INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI -3

Telephone No: 04425305301
Fax : 044 25363970

CERTIFICATE OF APPROVAL

To
Dr. K. Balamurugan
PG in MD Paediatrics
ICH/ Madras Medical College, Chennai

Dear Dr. K. Balamurugan

The Institutional Ethics Committee of Madras Medical College reviewed and discussed your application for approval of the proposal entitled " Prevalance of Prediabetes in urban school going adolescents aged 11-17 years with high risk factors" No. 14052012.

The following members of Ethics Committee were present in the meeting held on 30.05.2012 conducted at Madras Medical College, Chennai -3.

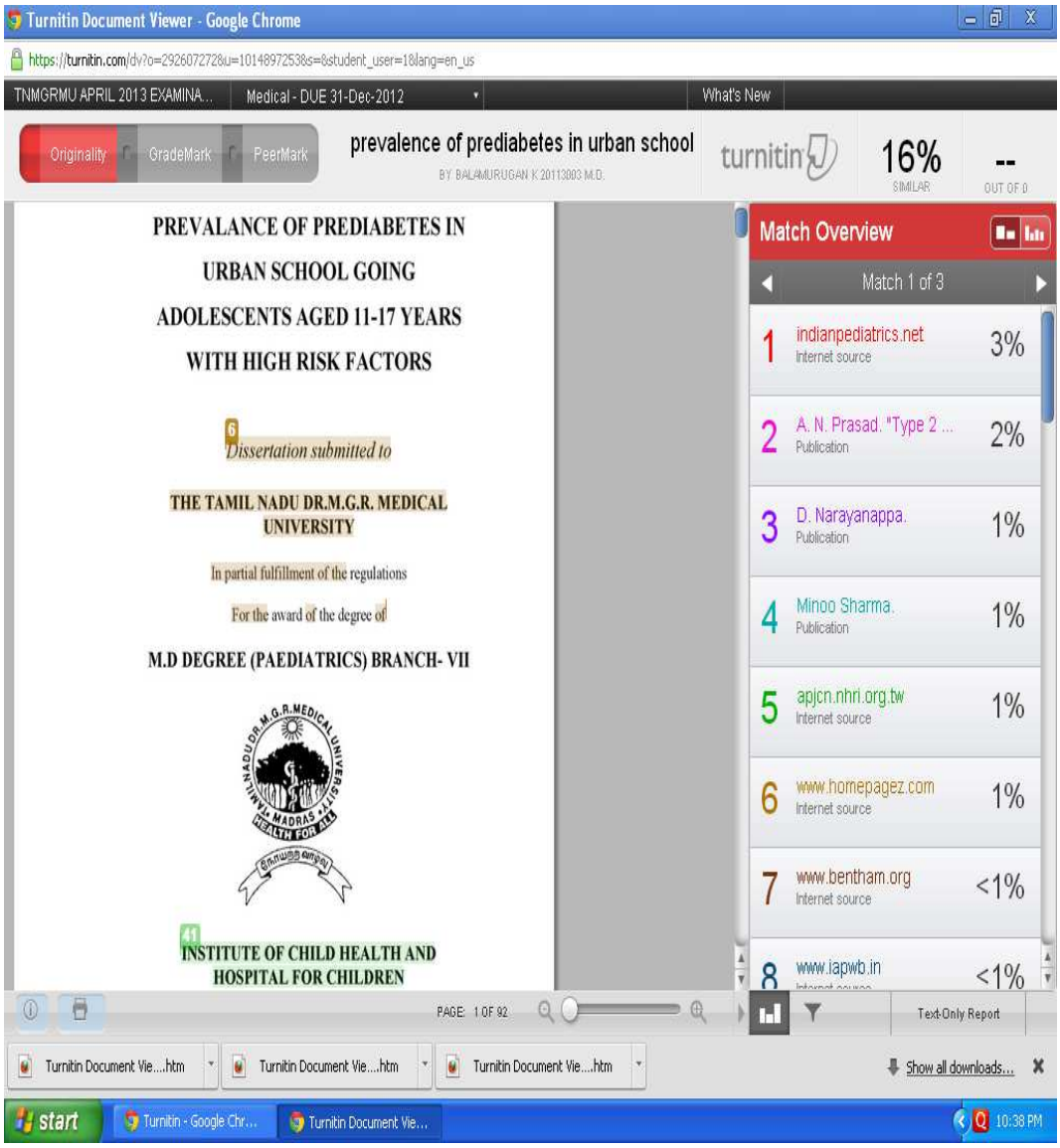
1.	Prof. S.K. Rajan, MD	-- Chairperson
2.	Prof. Pregna B. Dolia MD Vice Principal , Madras Medical College, Chennai -3 Director , Instt.of Bio Chemistry, MMC, Ch-3	-- Member Secretary
3.	Prof R. Nandhini, MD Director, Institute of Pharmacology, MMC, Ch-3	-- Member
4.	Prof. P. Karkuzhali MD Director i/c Prof & Head , Dept. of Pathology, MMC, Ch-3	-- Member
5.	Prof.A. Radhakrishnan MD Prof. of Internal Medicine, MMC, Ch-3	-- Member
6.	Prof. P. Raghumani MS Prof. of Surgery, Dept. of Surgery, MMC, Chennai -3	-- Member
7.	Thiru. S. Govindasamy . BA.BL	-- Lawyer
8.	Tmt. Arnold Soulina MA	-- Social Scientist

We approve the proposal to be conducted in its presented form.

Sd /. Chairman & Other Members

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information / informed consent and asks to be provided a copy of the final report

Member Secretary, Ethics Committee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THE TAMIL NADU DR.M.G.R. MEDICAL UNIVERSITY
In partial fulfillment of the regulations
For the award of the degree of
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