An analysis of lipid profile in pre-diabetes population of south India: A case of Telangana State

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ABSTRACT
Complications from diabetes, such as coronary artery and peripheral vascular disease, stroke, diabetic neuropathy, amputations, renal failure and blindness are resulting in increasing disability, reduced life expectancy and enormous health costs for virtually every society. Diabetes is certain to be one of the most challenging health problems in the 21st century. The country is already being dubbed as the “Diabetes Capital of the World.”

Pre-diabetes (comprise of IFG and IGT) is the state that occurs when a person’s blood glucose levels are higher than normal but not high enough for a diagnosis of diabetes. The terms IFG and IGT refer to an intermediate metabolic stage between normal glucose and diabetes.

The cross-sectional study was carried out in various locations of Telangana. The Researcher followed American Diabetic Association (ADA) criteria for defining the IFG and IGT. 1650 eligible subjects were selected for the study. Laboratory Investigations were done on subjects related to Fasting blood glucose, 2 h after Blood Glucose and lipid profile test.

The data was analyzed by using Chi square test using SAS version 8.2. Demographic background and baseline data was presented descriptively. All continuous variables like laboratory data was represented by mean ±SD (Standard Deviation).

Lipid abnormality is also reported in this population along with glucose abnormality. This study clearly indicates that, in this population along with glucose, we must focus on lipid abnormality corrections. Clinicians generally focus only on glucose, but we must focus on lipid too, to avoid the development of diabetes dyslipidemia. May be the stage can be classified as a pre dyslipidic/metabolic syndrome.

Keywords: Assessment, pre-diabetes, Impaired fasting glucose(IFG), Impaired glucose tolerance(IGT)

I. Introduction
Diabetes mellitus is characterized by high blood glucose levels that result from defects in the body's ability to produce or use insulin. It is a condition primarily defined by the level of hyperglycaemia which gives the risk of micro vascular damage includes retinopathy, nephropathy and neuropathy. It is coupled with reduced life expectancy, considerable morbidity due to specific diabetes associated microvascular complications, increased risk of macrovascular complications which includes heart disease, stroke and peripheral vascular disease, and reduced quality of life. Several pathogenetic processes are involved in the development of diabetes. These include processes, which destroy the beta cells of the pancreas with consequent insulin deficiency, and others that result in resistance to insulin action. The abnormalities of carbohydrate, fat and protein metabolism are due to deficient action of insulin on target tissues resulting from insensitivity or lack of insulin. Diabetes is the most common metabolic disorder, which is still incurable even today. Currently, type 2 diabetes mellitus is diagnosed when the underlying metabolic abnormalities consisting of insulin resistance and decreased β-cell function cause elevation of plasma glucose above 126 mg/dl (7 mmol/L) in the fasting state and/or above 200 mg/dl (11.1 mmol/L) 120 min after a 75-g glucose load.

However, the fact that many newly diagnosed type 2 diabetic subjects already suffer from so called “late complications of diabetes” at the time of diagnosis indicates that the diagnosis may have been delayed and, in addition, that the prediabetic condition is harmful to human health and requires increased awareness by physicians and the general public. Thus, type 2 diabetes mellitus represents only the “tip of the iceberg” of long existing metabolic disturbances with deleterious effects on the vascular system, tissues, and organs. Consequently, urgent efforts are required to avoid the growing number of patients with this form of a “silently killing” metabolic disease.

Complications from diabetes, such as coronary artery and peripheral vascular disease, stroke, diabetic neuropathy, amputations, renal failure and blindness are resulting in increasing disability, reduced life expectancy and enormous health costs for virtually every society. Diabetes is certain to be one of the most challenging health problems in the 21st century. The country is already being dubbed as the “Diabetes Capital of the World.”
Despite the morbidity and mortality associated with retinopathy, nephropathy, and neuropathy, cardiovascular disease remains the leading cause of death in type 2 diabetes mellitus. Consequently, the treatment of confounding risk factors of obesity, hypertension, and hyperlipidemia assumes major importance and must be coordinated with good glycemic control for reduction in total mortality in type 2 diabetes mellitus.

IGT is characterized by an increase in postprandial glucose levels, which is considered the initial metabolic abnormality in type 2 diabetes mellitus. It is one of a series of risk factors for Cardio Vascular Disease (hypertension, high triglyceride levels, low high-density lipoprotein-cholesterol and central obesity), known as the metabolic syndrome. The different factors making up this syndrome are intimately related. An impaired lipid profile can contribute to insulin resistance, as IGT may play a pathogenic role on other cardiovascular risk factors.

II. Materials and methods:
The cross-sectional study was carried out in various locations of Telangana. The Researcher followed American Diabetic Association (ADA) criteria for defining the IFG and IGT. Impaired Fasting Glucose (IFG) was defined as a fasting plasma glucose value of 100-125 mg/dl (5.6-6.9 mmol/L) in the absence of a previous diagnosis of diabetes.

Impaired Glucose Tolerance (IGT) was defined as a plasma glucose concentration of 140-200 mg/dl (7.8 to 11.0 mmol/L) two hours after oral administration of 75 gm of glucose in subjects, whose plasma glucose concentration after overnight fasting was less than 140 mg/dl.

2.1 Study documents preparation:
Protocol, ICF and CRF were prepared in consultation with the experts, Dr. B.S Reddy and Dr. C.R Reddy. Declaration of Helsinki principle was followed in the study. After the preparation of the documents, quality check was performed. The required copies were prepared and submitted to the ethics committee of OPJS University, Churu for its approval. An Informed consent form was prepared as per the regulatory requirement.

2.2 Case Record Form:
A survey questionnaire was administered to all the participating subjects to collect the detailed information.

2.2.2 Inclusion & Exclusion Criteria:
Inclusion Criteria:
- Age > 20 years

Exclusion Criteria:
- Diabetic Patients and Who are following diet, exercise and Oral hypoglycemic agents and Insulin also.

To obtain 1650 eligible subjects, approximately 1750 individuals (considering the drop out ratio of around 10%, for many reasons) more than > 20 years of age were screened from the different areas of Telangana. We also ensured that, we get the equal distribution from all the socio economic class, education class, field workers and office workers.

2.2.3 Laboratory Investigations: Following laboratory investigations were performed for all the individuals at the central laboratory. A qualified and trained doctor/phlebotomist collected the blood samples.
- a. LDL
- b). HDL
- c). Serum Triglycerides

2.3 Methodology followed during the Screening:
2.3.1. Activities carried out before camps (2 weeks before):
- Meeting with Local Community /School management.
- Meeting with Local medical doctor
- Registration of subjects for the purpose of study

2.3.2. Activities carried out during Camps:
- Taking the consent from subjects
- Collect the blood for investigations (Fasting stage)
- Administration of 75 gm Glucose dissolved in water
- After 2 hours blood collection

2.3.2.2 Laboratory Analysis:
After 10–12 hr of an overnight fast, each subject voided, and then the fasting blood sample was collected. A 75 gm anhydrous glucose dissolved in 250 ml of water was given orally over the course of 5 min and a second blood sample was drawn exactly 2 hours later for glucose estimation.
Blood for glucose determination was collected into tubes containing fluoride and EDTA. Throughout the study only one technician was allocated to avoid interpersonal error. These blood samples were immediately centrifuged and processed further.

2.4 Data entry:
CRFs were collected and stored at secured and access controlled place. After that, all the CRFs were reviewed second time for any discrepancies. Once check is over, the data entry was performed. Data entry was performed by using Microsoft Excel 2003

2.5 Statistical Analysis:
All statistical tests were considered significant at 5% level of significance. All data was analyzed by using Chi square test using SAS version 8.2.

Demographic background and baseline data was presented descriptively. All continuous variables like height, weight and laboratory data was represented by mean +SD (Standard Deviation). All the categorical variables were presented as counts and percentages.

III. Results:
Lipid profile analysis in Prediabetes Population:

Table 1: Summary of Lipid profile Analysis for Normoglycemic, IFG and newly diagnosed diabetes population:

<table>
<thead>
<tr>
<th>Category</th>
<th>Statistical Tool</th>
<th>Serum Cholesterol (mg/dl)</th>
<th>HDL Cholesterol (mg/dl)</th>
<th>LDL Cholesterol (mg/dl)</th>
<th>Serum Triglycerides (mg/dl)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normoglycemic (&lt;110 mg/dl)</td>
<td>N</td>
<td>1331</td>
<td>1330</td>
<td>1330</td>
<td>1330</td>
</tr>
<tr>
<td></td>
<td>MIN-MAX</td>
<td>31.41-360.51</td>
<td>14.00-57.21</td>
<td>66.90-225.31</td>
<td>10.00-170.01</td>
</tr>
<tr>
<td></td>
<td>MEAN±SD</td>
<td>203.01±38.24</td>
<td>44.55±4.38</td>
<td>131.55±25.57</td>
<td>141.60±76.73</td>
</tr>
<tr>
<td>IFG (&gt;110 &lt;126 mg/dl)</td>
<td>N</td>
<td>40</td>
<td>40</td>
<td>40</td>
<td>110</td>
</tr>
<tr>
<td></td>
<td>MIN-MAX</td>
<td>129.01-203.70</td>
<td>38.10-55.91</td>
<td>67.60-193.91</td>
<td>70.00-480.71</td>
</tr>
<tr>
<td></td>
<td>MEAN±SD</td>
<td>208.83±51.27</td>
<td>45.72±5.94</td>
<td>130.47±35.60</td>
<td>178.44±94.17</td>
</tr>
<tr>
<td>Newly Diagnosed Diabetes (&gt;126 mg/dl)</td>
<td>N</td>
<td>89</td>
<td>89</td>
<td>89</td>
<td>89</td>
</tr>
<tr>
<td></td>
<td>MIN-MAX</td>
<td>104.10-310.41</td>
<td>37.00-57.11</td>
<td>85.60-192.71</td>
<td>73.70-412.91</td>
</tr>
<tr>
<td></td>
<td>MEAN±SD</td>
<td>206.23±45.48</td>
<td>45.05±5.20</td>
<td>128.35±32.22</td>
<td>193.21±96.51</td>
</tr>
</tbody>
</table>

The data from the above table conforms that, Serum tryglycerides is highly significant statistically in IFG population as compare to normoglycemic population. These results also match with the findings from various empirical studies in the Indian population.

IFG population has more Serum tryglycerides, when it is compared to normoglycemic population. The findings from the data prove our hypothesis that, IFG population is more prone to develop dyslipidemia. Similarly for other lipid parameters such as Serum Cholesterol, HDL and LDL is also elevated in IFG population but statistically insignificant.

Table 2: Profile of normoglycemic, IFG and newly diagnosed diabetes population by their lipids:

<table>
<thead>
<tr>
<th>Category</th>
<th>Male Total</th>
<th>&lt;200</th>
<th>&lt;40</th>
<th>≥40</th>
<th>Female Total</th>
<th>&lt;200</th>
<th>&lt;40</th>
<th>≥40</th>
<th>&lt;50</th>
<th>≥50</th>
<th>&lt;130</th>
<th>≥130</th>
<th>Total</th>
<th>&lt;150</th>
<th>≥150</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fasting Blood Glucose</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Normoglycemic (&lt;110 mg/dl)</td>
<td></td>
<td>1441</td>
<td>714</td>
<td>728</td>
<td>554</td>
<td>717</td>
<td>136</td>
<td>587</td>
<td>66</td>
<td>520</td>
<td>1440</td>
<td>725</td>
<td>110</td>
<td>22</td>
<td>22</td>
</tr>
<tr>
<td>IFG (&gt;110 &lt;126 mg/dl)</td>
<td></td>
<td>40</td>
<td>20</td>
<td>20</td>
<td>20</td>
<td>23</td>
<td>5</td>
<td>10</td>
<td>4</td>
<td>6</td>
<td>40</td>
<td>12</td>
<td>10</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Newly Diagnosed Diabetes (&gt;126 mg/dl)</td>
<td></td>
<td>86</td>
<td>43</td>
<td>43</td>
<td>43</td>
<td>41</td>
<td>4</td>
<td>10</td>
<td>7</td>
<td>6</td>
<td>86</td>
<td>50</td>
<td>35</td>
<td>25</td>
<td>25</td>
</tr>
<tr>
<td>P value</td>
<td></td>
<td>0.005</td>
<td>0.456</td>
<td>0.695</td>
<td>0.009</td>
<td>0.0254</td>
<td>0.0001</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The above table illustrates that, subjects with Serum triglycerides more than equal to 150 have more chances for development of Impaired Fasting Glucose. P-value = <0.001, is calculated by using chi-square test, which indicates that the association is statistically highly significant.

**Table 3: Summary of Lipid Analysis for IGT population:**

<table>
<thead>
<tr>
<th>Category</th>
<th>Statistical Tool</th>
<th>Serum Cholesterol (mg/dl)</th>
<th>HDL Cholesterol (mg/dl)</th>
<th>LDL Cholesterol (mg/dl)</th>
<th>Serum Triglycerides (mg/dl)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2h Post Glucose</td>
<td>N</td>
<td>1359</td>
<td>1358</td>
<td>1358</td>
<td>1369</td>
</tr>
<tr>
<td>&lt;140 mg/dl</td>
<td>MIN-MAX</td>
<td>31.40-360.50</td>
<td>14.60-57.70</td>
<td>65.80-225.30</td>
<td>59.30-870.10</td>
</tr>
<tr>
<td></td>
<td>MEAN=SD</td>
<td>203.39±39.10</td>
<td>44.64±4.78</td>
<td>131.70±26.10</td>
<td>143.91±74.01</td>
</tr>
<tr>
<td>II: Impaired Glucose N</td>
<td>MIN-MAX</td>
<td>129.90-87.40</td>
<td>37.00-50.10</td>
<td>67.60-188.40</td>
<td>72.10-489.70</td>
</tr>
<tr>
<td>Tolerance(IGT) (2 h post glucose 140-200 mg/dl)</td>
<td>MEAN=SD</td>
<td>199.88±39.07</td>
<td>44.32±4.36</td>
<td>124.02±28.07</td>
<td>175.23±77.12</td>
</tr>
</tbody>
</table>

Category I: Subjects after 2 hr post glucose value < 140 mg/dl. Category II: Subjects with 2 hr post glucose value 140-200 mg/dl (Impaired glucose Tolerance) * 58 subjects with 2 hr blood glucose value more than 200 mg/dl were excluded from the analysis.

The above mentioned data suggest that, there is significant difference in Serum triglycerides value in Category I as compared to IGT population.

IGT population also has more Serum triglycerides, as compare to category I. The above result from the findings proves our hypothesis that IGT population is more prone to develop diabetic dyslipidemia. These findings could be unique for Telagana population that, they have higher triglycerides. Other laboratory parameters may be found abnormal but our study has highlighted about triglycerides and it is genetically match with Indian population, where they have been labelled with hypertriglyceridemia. We can also hypothesize that, other laboratory parameters may be found abnormal after the age of 60 years.

**Table 4: Profile of IGT population by their lipids:**

<table>
<thead>
<tr>
<th>Category</th>
<th>Serum Cholesterol (mg/dl)</th>
<th>HDL Cholesterol (mg/dl)</th>
<th>LDL Cholesterol (mg/dl)</th>
<th>Serum Triglycerides (mg/dl)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Male</td>
<td>Female</td>
<td>Male</td>
<td>Female</td>
</tr>
<tr>
<td>----------</td>
<td>---------------------------</td>
<td>------------------------</td>
<td>------------------------</td>
<td>---------------------------</td>
</tr>
<tr>
<td>2 h Post Glucose</td>
<td>Total</td>
<td>&lt;200</td>
<td>&lt;200</td>
<td>Total</td>
</tr>
<tr>
<td>2 h Post Glucose</td>
<td>1297 (100)</td>
<td>860 (49.38)</td>
<td>697 (50.62)</td>
<td>808 (100)</td>
</tr>
<tr>
<td>2 h Post Glucose</td>
<td>1.85 (93.54)</td>
<td>634 (40.64)</td>
<td>634 (47.49)</td>
<td>762 (94.31)</td>
</tr>
<tr>
<td>Impaired Glucose Tolerance&lt;1 GT (2 h post glucose &gt;140 mg/dl)</td>
<td>89 (6.46)</td>
<td>46 (3.34)</td>
<td>43 (3.12)</td>
<td>46 (5.69)</td>
</tr>
<tr>
<td>P-value</td>
<td>0.8905</td>
<td>0.9235</td>
<td>0.1027</td>
<td>0.2713</td>
</tr>
</tbody>
</table>

The above table-13 shows that, subjects with triglycerides value more than 150 have more chances to develop Impaired Glucose Tolerance 54 (3.85%) against 36 (2.62%). P-value = <0.001, is calculated by using chi-square test, which indicates that the association is statistically highly significant.

For HDL, in the group of male subjects with HDL less than 40 have more chances of development of Impaired Glucose Tolerance 39 (4.83%) against 7 (0.87%). p-value =0.9235 indicates this association is statistically insignificant.

**IV. Discussion**

The Adult Treatment Panel III of the National Cholesterol Education Program has identified metabolic syndrome as a constellation of lipid and non lipid risk factors for coronary artery disease. The syndrome is characterized by insulin resistance, atherogenic dyslipidemia (high triglyceride level, low high-density lipoprotein cholesterol level, and small, dense low density lipoprotein cholesterol particles), hypertension, abdominal obesity and prothrombotic and proinflammatory states.
Compared with normoglycemic persons, patients with IGT are at substantially higher risk of developing cardiovascular disease. We have also counseled all the subjects to have control diet mainly to limit the carbohydrate to reduce the serum triglycerides. Changes in serum triglyceride and HDL cholesterol were more favorable with the low-carbohydrate diets.

In one similar study, subjects with type 2 diabetes demonstrated a greater decrease in A1C with a low carbohydrate diet than with a low-fat diet.

Plasma levels of LDL generally do not differ significantly from those in patients without diabetes, but qualitative changes in LDL particles make them highly atherogenic. From our study, we also noticed that LDL is not much altered. However, we have noticed more changes in Serum Tryglyceride. In IFG the mean Serum Tryglyceride is 178.44 + 94.18 mg/dl and in IGT it is 175 + 77.12 mg/dl. These results are highly correlated with Indian population.

The primary goal with respect to dietary fat in individuals with diabetes is to limit saturated fatty acids, trans fatty acids, and cholesterol intake, so as to reduce risk for Cardiovascular Diseases (CVD). Strategies that improve insulin resistance and enhance early insulin secretion may prevent the progression from IGT to diabetes. Already, there is substantial evidence the weight loss and exercise may reduce the risk of developing diabetes by up to 58%.

HDL has the inverse relation, states that HDL is more in IFG and IGT population as compare to the normoglycemic. In the contrary, other lipid parameters such as LDL, serum cholesterol and serum triglycerides are elevated in IFG and IGT population and have the direct relationship with dyslipidemia and prediabetes. And may lead to diabetes dyslipidemia in the long run.

The management plan should be formulated as a collaborative therapeutic alliance among the patient and family, the physician and other members of the health care team. A variety of strategies and techniques should be used to provide adequate education and development of problem-solving skills in the various aspects of prediabetes management early stage. There may be possible limitation of the study due to the sample size.

V. Conclusion

Lipid abnormality is also reported in this population along with glucose abnormality. This clearly indicates that in this population along with glucose, we must focus on lipid abnormality corrections. Clinicians generally focus only on glucose, but we must focus on lipid too, to avoid the development of diabetes dyslipidemia. May be the stage can be classified as a pre dyslipidic/metabolic syndrome.

References:

