Introduction
Diabetes mellitus type 2 (DM2) is becoming a global public health challenge for the 21st century, as a non-communicable disease[1]. DM2 is a metabolic disorder resulting from defect in insulin secretion or action and is characterized by hyperglycemia often accompanied by glycosuria, polydipsia, polyuria[2, 3, 4]. The prevalence shows DM2 incidence is increasing sharply, reaching pandemic proportions influencing world health care system. Different researches evident that a majority of patients are not achieving the targeted blood glucose level causing a high prone for vascular complications[5]. Hyperglycemia in DM2 causes oxidative stress, by damage to lipoprotein, components of cell membrane, chromosomal DNA, which may increases the atherosclerosis risk [6,7].

Vitamin E(vit-E) is a fat soluble antioxidant, found virtually in all cell membranes, neutralizes the free radicals, which reduces reactive oxygen species (ROS) production[8]. Different studies reported that in T2DM patients’ serum vit-E level is lower as compared to healthy individuals [9, 10, 11]. Several studies also postulate that vit E has beneficial effects in DM2 and different diseases[12, 13]. Still there are limited studies of its effect on glycaemic control and vascular risk factors in Indian population[14], and this study was designed to know the effect of oral vit E supplementation on glycaemic control and lipid profile in patients with DM2 from Khurda district, Odisha.

Materials & Methods
The design was prospective randomized controlled trial, involving type 2 DM patients attending Endocrinology Department, IMS & SUM Hospital, Bhubaneswar. The study duration was between Aug 2013- Aug 2014. A total of 123 DM2 patients taking insulin as their treatment were enrolled for the study. DM2 patients of either sex with or without macro- and micro-vascular complications and taking insulin were included in this trial. Patients age less than 25 years, uncontrolled hypertension, myocardial infarction, stroke within one month before enrollment, known allergy to vit-E were excluded from the study. Out of 123 enrolled patients, 43 were excluded as they were taking oral anti-diabetic drugs also. Out of 80 T2DM cases, 50 were randomized to supplement with vit-E capsule orally (1000 IU/day) and 30 age-matched patients were supplemented with placebo for 6weeks. FBS, PPBS, Total Cholesterol, Triglyceride, Low density Lipoprotein, High Density Lipoprotein, Very Low Density Lipoprotein were measured before and after supplementation and results were analyzed. Results & Conclusion: A significant decrease in FBS, TG, LDL was seen in group supplemented with 1000 I.U. vit-E/day, which indicates vit-E may be beneficial in DM2 patients.

Results

The Table-1 shows the value of both group and their P-values, when tested between both I+E and I-groups putting student’s t-test. All data are presented as mean ± standard deviation (M ± SD). The difference of FBS in both insulin with vit-E group and only insulin treated groups are not significant, which shows our study groups are from same population. The FBS level decreased significantly in I+E group (P<0.001) than the insulin alone group. The PPBS level (mg/dl) in both groups before starting treatment shows no significant difference. When compared between both groups, it shows a insignificant decrease in PPBS level. The Tg level (mg/dl) significantly more in case of I+E group than I-group alone. However total cholesterol levels, HDL, LDL, VLDL levels comparison shows no significant difference between both groups, both before and after treatment.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>I+E (0 wk)</th>
<th>I (0 wk)</th>
<th>P</th>
<th>I+E (6 wk)</th>
<th>I (6 wk)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>FBS (mg/dl)</td>
<td>162.98 ± 32.88</td>
<td>175.07 ± 31.84</td>
<td>NS</td>
<td>141.80 ± 20.24</td>
<td>167.47 ± 32.67</td>
<td>0.001</td>
</tr>
<tr>
<td>PPBS (mg/dl)</td>
<td>216.28 ± 50.72</td>
<td>215.07 ± 32.59</td>
<td>NS</td>
<td>199.50 ± 34.8</td>
<td>205.07 ± 36.77</td>
<td>NS</td>
</tr>
<tr>
<td>TG (mg/dl)</td>
<td>161.94 ± 59.33</td>
<td>147.97 ± 43.30</td>
<td>NS</td>
<td>149.48 ± 54.07</td>
<td>164.33 ± 49.48</td>
<td>0.001</td>
</tr>
<tr>
<td>TCH (mg/dl)</td>
<td>183.04 ± 47.24</td>
<td>179.07 ± 36.57</td>
<td>NS</td>
<td>177.14 ± 42.51</td>
<td>186.47 ± 33.39</td>
<td>NS</td>
</tr>
<tr>
<td>HDL (mg/dl)</td>
<td>40.56 ± 4.97</td>
<td>42.57 ± 5.26</td>
<td>NS</td>
<td>41.70 ± 5.15</td>
<td>42.00 ± 3.72</td>
<td>NS</td>
</tr>
<tr>
<td>LDL (mg/dl)</td>
<td>105.32 ± 43.59</td>
<td>108.27 ± 36.01</td>
<td>NS</td>
<td>102.44 ± 38.81</td>
<td>107.47 ± 32.24</td>
<td>NS</td>
</tr>
<tr>
<td>VLDL (mg/dl)</td>
<td>31.96 ± 12.49</td>
<td>32.53 ± 8.90</td>
<td>NS</td>
<td>28.72 ± 10.44</td>
<td>31.60 ± 9.35</td>
<td>NS</td>
</tr>
</tbody>
</table>

The table-2 shows the values of both groups and their P-values, when tested within the same groups before and after the treatment putting
student’s paired t-test. It shows after 6 weeks of supplementation of vitamin E with insulin, the fasting blood sugar decreased very much significantly (P < 0.001). While in only insulin treated case, the decrease is insignificant decrease. The TCH, HDL, LDL level within the groups, before and after treatment, shows no significant difference. But VLDL level decreased significantly in I + E group after 6 weeks of therapy. But however the rate of decrease is not significant as compared to insulin alone group.

### Discussion

From this study, it was found that vitamin E supplementation significantly decreases FBS and PPBS level in comparison to only insulin treated group. The TG and VLDL levels also decreases significantly with 6 weeks of vitamin E supplement in DM2. However the study fails to find any significant change in TCH, HDL and LDL levels. According to Suksomboon N et al, vitamin E supplementation did not improve glycaemic control in the full set of type 2 diabetes patients. It was effective only in a subgroup of patients with inadequate glycaemic control at baseline (HbA1c > 8%) and in those whose baseline serum vitamin E levels were below normal ranges [15].

We observed that serum vitamin E was significantly reduced after vitamin E supplementation in intervention group as compared with controlled group. This result is in agreement with some previous reports on type 2 diabetic patients [12, 13, 16-18]. SPACE study in haemodialysed patients, who have very high levels of oxidative stress, demonstrated significant cardioprotective effect of vitamin E in type 2 diabetes patients [19]. It was effective only in a subgroup of patients with inadequate glycaemic control at baseline (HbA1c > 8%) and in those whose baseline serum vitamin E levels were below normal ranges [15].

### References:


