A Comparative Evaluation of Safety and Efficacy of Rosuvastatin, Atorvastatin and Salveo Andaman Noni (Freeze Dried)

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ABSTRACT
Salveo Andaman Noni is the freeze dried ripe fruits of Morinda citrifolia grown in Andaman. Objective of this Open labelled, non-randomized Comparative study was to establish the efficacy and Safety of statins (Rosuvastatin, Atorvastatin) verses Salveo Andaman Noni in patients with coronary heart disease or multiple risk factors for coronary heart disease. The trial was designed and conducted in accordance with ethical principles of Good Clinical Practice. Total Study Duration was of 3 months. Each patient was given either Rosuvastatin or Atorvastatin or Salveo Andaman Noni according to the treatment regimen prescribed by the physician. The initial value of LDL-C was taken. It was considered as the baseline value. First review value of LDL-C was taken at the end of the 1st month of starting the treatment. The baseline, first review values of Statin (Rosuvastatin or Atorvastatin) are compared with Salveo Andaman Noni for each patient. Total cholesterol, Triglyceride, HDL-C levels evaluated after every 1 month for a period of 3 months. Comparison of the review values was done for Atorvastatin and Rosuvastatin. A significant reduction in lipid level was noticed in patients after treatment with Salveo Andaman Noni. However statin drugs were more effective in reduction in lipid levels. Comparative Analysis of effect of Rosuvastatin (10mg,20mg), Atorvastatin (10mg,20mg) vs. Salveo Andaman Noni (Freeze dried) in lowering LDL-C, Total Cholesterol, Triglyceride level against baseline value is established.

Keywords: Rosuvastatin, Atorvastatin, Noni, Hyperlipidemia.

1. INTRODUCTION
Coronary heart disease is increasing in Indian subjects and lipid abnormalities are important risk factors. Hyperlipoproteinemia is one of the leading causes of ischemic heart disease, myocardial infarction and cerebral vascular accidents. Cardiovascular diseases, especially coronary heart disease, are important public health problems in India. There is evidence that the diseases are increasing in India contrast to developed nations of Europe and North America where then incidence has decreased.

The hypolipidaemic drugs have attracted considerable attention because of their potential to prevent cardiovascular disease by retarding the accelerated atherosclerosis in hyperlipidemic individuals. Lipids are carried in plasma in lipoproteins after getting associated with several Apoproteins; plasma lipid concentrations are dependent on the concentration of Lipoproteins. The core of lipoproteins globules consists of triglycerides (TGs) or Cholesterol esters (CHEs) while the outer polar layer has phospholipids, free cholesterol (CH) and apoproteins. The lipoproteins have been divided into 6 classes on the basis of their particle size and density. They are Chy-Chylomicrons; Chy rem- Chylomicron remnant; VLDL- Very low density lipoproteins; LDL- Low density lipoprotein, CHE- Cholesteryl esters, TG- triglyceride; CH-Cholesterol¹.

¹Reference(s)
Each class of lipoprotein has a specific role in lipid transport, and they are different pathways for exogenous and for endogenous lipids, as well as a pathway for reverse cholesterol transport. The pathways are distinguished by the main apoproteins (apoB-48, apoB-100 and apoA1, respectively) that are ligands for the key receptors. In exogenous pathway, cholesterol and triglycerides absorbed from the ileum are transported as chylomicrons (diameter 100-1000 nm), in lymph and then blood, to capillaries in muscle and adipose tissue. Here, triglycerides are hydrolyzed by lipoprotein lipase, and the tissue takes up the resulting free fatty acids and glycerol. In endogenous pathway, cholesterol and the newly synthesized triglycerides are transported from liver as VLDL (diameter 30-80nm) to muscle and adipose tissue, where triglycerides is hydrolyzed to fatty acids and glycerol; these enter the tissues as described above. Consequently, they increase in the density to intermediate-density cholesterol and but ultimately LDL-C particles. LDL-C provides the source of the cholesterol for incorporation into cell membranes and for synthesis of steroids but is also key in atherogenesis. Cells take up LDL-C by endocytosis via LDL receptors that recognize LDL apolipoproteins. Some drugs (notably statins; see below) reduce circulating LDL-C by inhibiting endogenous cholesterol synthesis and stimulating the synthesis of hepatic LDL receptors. Cholesterol can return to plasma from the tissues in HDL particles (diameter 7-20 nm). Cholesterol is esterified with long-chain fatty acids in HDL particles, and the resulting cholesteryl esters are transferred to VLDL or LDL particles by a transfer protein present in the plasma and known as cholesteryl ester transfer protein (CETP).

Lipoprotein (a), or Lp(a), is a species of LDL that is strongly associated with atherosclerosis and is localised in atherosclerotic lesions. Lp(a) contains a unique apoprotein, apo(a), with structural similarities to plasminogen. Lp(a) competes with and inhibits the binding of plasminogen to its receptors on the endothelial cell. Plasminogen is normally the substrate for plasminogen activator, which is secreted by and bound to endothelial cells, generating the fibrinolytic enzyme plasmin. The effect of the binding of Lp(a) is that less plasmin is generated, fibrinolysis is inhibited and thrombosis promoted. Study of familial hypercholesterolemia enabled Brown & Goldstein to define the LDL receptor pathway of cholesterol homeostasis (for which they shared a Nobel Prize) in patients with raised TG levels, rosuvastatin raises HDL-CH by 15-20% (greater rise than other statins). Short-acting statins given by mouth at night to reduce peak cholesterol synthesis in the Early morning. They are well absorbed and extracted by liver, their site of action, and are subject to extensive presystemic metabolism via cytochrome P450 and glucuronidation pathways. All statins are remarkably well tolerated. However, Muscle tenderness and rise in CPK levels occurs infrequently by statins. Myopathy is the only serious reaction, but is rare « 1 per 1000). Statins are the first choice drugs for primary hyperlipidaemias with raised LDL and total CH levels, with or without raised TG levels (Type ITa, IIb, V), as well as for secondary (diabetes, nephrotic syndrome) hypercholesterolemia.

Efficacy of statins in reducing raised LDL-CH associated mortality and morbidity is now well established.

MATERIALS & METHODS
1. NONI

Plants are the reservoirs of a large number of compounds and have long been used as the sources of medicines. Among the medicinal plants Noni (Morinda citrifolia) is one of the important traditional folk medicinal plants. All parts of the noni plant have traditional and/or modern uses, including roots and bark (dyes, medicine), trunks (firewood, tools), and leaves and fruits (food, medicine). The medicinal applications, both traditional and modern, span a vast array of conditions and illnesses, although most of these have yet to be scientifically supported. It has been reported to have a broad range of therapeutic and nutritional value [8,9,10,11,12,13,14, 15,16, 17, 18, 19,20,21]. Salveo Andaman Noni is the
freeze dried ripe fruits of Noni grown in Andaman.

Fig. 1: Plant of Noni (Morinda citrifolia)

2. STATINS
HMG-CoA reductase inhibitors
ATORVASTATIN, ROSUVASTATIN

Introduced in the 1980s, these classes of compounds are the most efficacious and best tolerated hypolipidaemic drugs. They competitively inhibit conversion of 3-Hydroxy-3-methyl glutaryl coenzyme A (HMG-CoA) to mevalonate (rate limiting step in CH synthesis) by the enzyme HMG-CoA reductase. Therapeutic doses reduce CH synthesis by 20-50%. This results in compensatory increase in LDL receptor expression on liver cells increased receptor mediated uptake and catabolism of IDL and LDL. Over long-term, feedback induction of HMG-CoA reductase tends to increase CH synthesis, but a steady-state is finally attained with a dose-dependent lowering of LDL-CH levels.

3. STUDY PROTOCOL
AIMS & OBJECTIVE
1. Comparison of safety and efficacy of Statin (Rosuvastatin, Atorvastatin) versus Salveo Andaman Noni.
2. Comparison of efficacy of Rosuvastatin versus Atorvastatin (doses as prescribed by the physician) in patients with coronary heart disease or multiple risk factors for coronary heart disease.

DESIGN
Open labelled, non-randomized Comparative study of Efficacy and Safety statins (Rosuvastatin, Atorvastatin) verses Salveo Andaman Noni will be carried out in a tertiary care setting in kolkata, 2012. Open-label: - A clinical trial in which doctors and participants know which drug is being administered. Non-Randomized:- Non-randomization is a process in which patients or subjects taking drug accordingly to treatment regiment. Comparison study means compare of the study drugs in the study. Efficacy defined as the maximum ability of a drug or treatment to produce a result regardless of dosage. A drug passes efficacy trails if it is effective at dose tested and against the illness for which it is prescribed. In this procedure mandated by the FDA, Phase ii clinical trails gauge efficacy, and phase iii trails confirm it.

STUDY DURATION
Total Study Duration: 3 months
Phases of Treatment:
- Visit 1: Screening Phase: Patients are to be screened according to the inclusion and exclusion criteria. Week-1.
- Treatment Phase: 12 Weeks.
- Visit 3: 12 weeks after starting treatment.
- End of Study.

STUDY TREATMENT
There will be five subgroups:
- Treatment 1: Rosuvastatin tablet (10mg), OD
- Treatment 2: Rosuvastatin tablet (20mg), OD
- Treatment 3: Atorvastatin tablet (10mg), OD
- Treatment 4: Atorvastatin tablet (20mg), OD
- Treatment 5: Salveo Andaman Noni freeze dried powder (3.5 gm), BD
SETTING
Medica SuperSpecialty Hospital, a tertiary care setup in Kolkata.
Medica Superspecialty Hospital, a unit of Medica Synergic Pvt. Ltd. and one of the largest integrated healthcare delivery providers in eastern India, brings you the finest ambience and services for inpatient and outpatient treatment.

INCLUSION CRITERIA
Atorvastatin
* Adult patients without clinically evident CHD, but with multiple risk factors for coronary heart disease such as age, smoking, hypertension and low HDL-C or family history of early coronary heart disease.
* Patients without clinically evident coronary heart disease, but with multiple risk factors for CHD such as retinopathy, albuminuria, smoking or hypertension.
* Patients with clinically evident CHD

Rosuvastatin
- Patients with elevated Total –C, LDL-C, Apo B, Patients with hyperlipidaemia or mixed dyslipidaemia.
- Patients with hyperlipidaemia or mixed dyslipidaemia.
- Patients with hypercholesterolemia.
- Individuals without clinically evident coronary heart disease but with an increased risk of cardiovascular disease based on age with the presence of at least one additional cardiovascular risk factor such as hypertension, low HDL-C, smoking or a family history of premature coronary heart disease.

EXCLUSION CRITERIA
- Paediatric patients.
- Nursing Mothers.
- Pregnant women or women of child bearing age.
- Hypersensitive to any component of the medication.

OUTCOME MEASURE
Primary Endpoint Measure
Reduction of LDL-C levels
- Each patient is given either Rosuvastatin or Atorvastatin or Salveo Andaman Noni according to the treatment regimen prescribed by the physician.
- The initial value of LDL-C has taken. It was considered as the baseline value. First review value of LDL-C will be taken at the end of the 1st month of starting the treatment. The baseline, first review values of Statin (Rosuvastatin or Atorvastatin) are to be compared with Salveo Andaman Noni for each patient.

Secondary Endpoint Measure
- Total cholesterol, Triglyceride, HDL- C levels will be evaluated after every 1 month for a period of 3 months.
- Comparison of the review values will be done for Atorvastatin and Rosuvastatin.

Methodology
Trial Design
This 12 Weeks Open labelled, non-randomized Comparative study was conducted from June 2012 to August 2012, at Medica Super specialty Hospital, kolkata, India. Patients non-randomized to Statin (Rosuvastatin or Atorvastatin) or Salveo Andaman Noni were given accordingly treatment regimen by physician for 12 weeks.

Ethical Consideration
The trial was design and conducted in accordance with Declaration of Helsinki (version amended October 2000) and in compliance with the ethical principles of Good Clinical Practice. Appropriate ethics committees or institutional review board approved the research protocol. All patients gave their written informed consent before initiation of any trial procedure. The identity of the patients shall not be disclosed. The protocol of this study has been approved by the ethical committee of the hospital.
Patients
Men and non-pregnant women with hypercholesterolemia who were more than 18 years of age were included in this study. Patients were taking those who had more than normal value of cholesterol, LDL, Triglycerides. Patients report their lipid profile test at end of 1st month after starting the treatment.

Statistical Analysis
All the values were expressed in Mean ± SD. Data were analyzed using student t-test to ascertain differences in efficacy between treatment groups and in incidence of adverse event. A p-value of <0.05 was considered to be statistically significant.

RESULTS
Effect of Salveo Andaman Noni (freeze dried) Vs. Rosuvastatin (10 mg, 20 mg) and Atorvastatin (10 mg, 20 mg) in lowering lipid profile:
A significant reduction in lipid level was noticed in patients after treatment with Salveo Andaman Noni. However statin drugs were more effective in reduction in lipid levels. Comparative Analysis of Effect of Rosuvastatin (10mg,20mg), Atorvastatin (10mg,20mg) vs. Salveo Andaman Noni (Freeze dried) in lowering LDL-C, Total Cholesterol, Triglyceride level against baseline value is depicted in Graphs 1.1, 1.2, 1.3 respectively.

But at the same time, the level of HDL-C was significantly increased by Salveo Andaman Noni (freeze dried) as compared to Rosuvastatin 10 mg, Atorvastatin (10 mg, 20 mg).[Graph 1.4].

Rosuvastatin, atorvastatin, and salveo Andaman noni (freeze dried) were very effective in reducing the levels of serum cholesterol, serum triglyceride, LDL, and VLDL after treatment for 12 weeks in

Graph 1.1: Comparison of Rosuvastatin (10 mg, 20 mg), Atorvastatin (10 mg, 20 mg) and Salveo Andaman Noni (freeze dried) against Baseline value (without drug) in Lowering Total Cholesterol Level

Graph 1.2: Comparison of Rosuvastatin (10 mg, 20 mg), Atorvastatin (10 mg, 20 mg) and Salveo Andaman Noni (freeze dried) against Baseline value (without drug) in Lowering Triglyceride Level

Graph 1.3: Comparison of Rosuvastatin (10 mg, 20 mg), Atorvastatin (10 mg, 20 mg) and Salveo Andaman Noni (freeze dried) against Baseline value (without drug) in Increasing HDL-C Level
patients with coronary heart disease or multiple risk factors for coronary heart disease with dyslipidaemia. The reductions in these lipid parameters were highly significant. Rosuvastatin, atorvastatin, and salveo Andaman noni (freeze dried) also increased the levels of HDL significantly ($P<0.001$) after treatment for 12 weeks.

Table 1: Comparative effect of rosuvastatin (10mg, 20mg), atorvastatin (10mg, 20mg), and salveo Andaman noni lipid profile parameter before therapy

<table>
<thead>
<tr>
<th>Lipid Levels</th>
<th>Rosuvastatin 10mg</th>
<th>Atorvastatin 10mg</th>
<th>Rosuvastatin 20mg</th>
<th>Atorvastatin 20mg</th>
<th>Salveo Andaman Noni</th>
</tr>
</thead>
<tbody>
<tr>
<td>LDL-C (mg/dl)</td>
<td>134.60 ± 17.84</td>
<td>132 ± 36.95</td>
<td>205.20 ± 9.67</td>
<td>104.80 ± 10.32</td>
<td>132.91 ± 35.88</td>
</tr>
<tr>
<td>TG (mg/dl)</td>
<td>216.20 ± 24.87</td>
<td>145.6 ± 8.08</td>
<td>294 ± 28.87</td>
<td>180.60 ± 49.08</td>
<td>210.4 ± 41.84</td>
</tr>
<tr>
<td>TG (mg/dl)</td>
<td>186.8 ± 39.85</td>
<td>79.2 ± 6.76</td>
<td>192.2 ± 41.96</td>
<td>291.20 ± 157.98</td>
<td>150.08 ± 57.36</td>
</tr>
<tr>
<td>HDL-C (mg/dl)</td>
<td>39.8 ± 7.98</td>
<td>44.4 ± 12.81</td>
<td>45.2 ± 1.64</td>
<td>33 ± 1.87</td>
<td>40.15 ± 8.44</td>
</tr>
</tbody>
</table>

Values are expressed as Mean ± SD.

Table 2: Comparative effect of rosuvastatin (10mg, 20mg), atorvastatin (10mg, 20mg), and salveo Andaman noni lipid profile parameter after therapy

<table>
<thead>
<tr>
<th>Lipid Levels</th>
<th>Rosuvastatin 10mg</th>
<th>Atorvastatin 10mg</th>
<th>Rosuvastatin 20mg</th>
<th>Atorvastatin 20mg</th>
<th>Salveo Andaman Noni</th>
</tr>
</thead>
<tbody>
<tr>
<td>LDL-C (mg/dl)</td>
<td>109.60 ± 11.12</td>
<td>111.6 ± 23.71</td>
<td>104.4 ± 6.34</td>
<td>59.4 ± 15.91</td>
<td>116.75 ± 34.28</td>
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<tr>
<td>TC (mg/dl)</td>
<td>191.2 ± 23.71</td>
<td>126.20 ± 7.79</td>
<td>104.40 ± 27.51</td>
<td>126 ± 46.83</td>
<td>179.83 ± 36.95</td>
</tr>
<tr>
<td>TG (mg/dl)</td>
<td>162 ± 21.08</td>
<td>67.2 ± 1.78</td>
<td>109.80 ± 34.42</td>
<td>196.8 ± 84.86</td>
<td>136.41 ± 55.73</td>
</tr>
<tr>
<td>HDL-C (mg/dl)</td>
<td>42.2 ± 6.94</td>
<td>46 ± 11.68</td>
<td>56 ± 5.83</td>
<td>35.2 ± 2.58</td>
<td>48.25 ± 9.35</td>
</tr>
</tbody>
</table>

Table 3:

<table>
<thead>
<tr>
<th>Lipid Levels</th>
<th>Rosuvastatin 10mg</th>
<th>Atorvastatin 10mg</th>
<th>Rosuvastatin 20mg</th>
<th>Atorvastatin 20mg</th>
<th>Salveo Andaman Noni</th>
</tr>
</thead>
<tbody>
<tr>
<td>LDL-C (mg/dl)</td>
<td>↓18.08 %</td>
<td>↓16.25 %</td>
<td>↓49.12 %</td>
<td>↓43.97 %</td>
<td>↓12.64 %</td>
</tr>
<tr>
<td>TG (mg/dl)</td>
<td>↑11.63 %</td>
<td>↑13.33 %</td>
<td>↑44.35 %</td>
<td>↑31.06 %</td>
<td>↑10.15 %</td>
</tr>
<tr>
<td>TG (mg/dl)</td>
<td>↑11.45 %</td>
<td>↑14.76 %</td>
<td>↑43.93 %</td>
<td>↑28.38 %</td>
<td>↑10.11 %</td>
</tr>
<tr>
<td>HDL-C (mg/dl)</td>
<td>↑16.73 %</td>
<td>↑14.49 %</td>
<td>↑23.66 %</td>
<td>↑16.59 %</td>
<td>↑19.92 %</td>
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</table>

Effect of Salveo Andaman Noni Vs Statin Drugs (Rosuvastatin and Atorvastatin) on liver enzymes

Atorvastatin 20 mg had increased the liver enzyme levels after 3rd month of treatment. But Salveo Andaman Noni did not increase the liver enzyme levels ($p<0.05$). The SGPT and SGOT levels were seen to increase in few 3 patients out of the total patients treated with statin, whereas at the same time no such incidences of increase in SGPT or SGOT levels were reported in patients treated with Noni. [Graphs 2.1, 2.2]
Comparison of efficacy between Atorvastatin and Rosuvastatin in lowering lipid levels

LDL cholesterol was reduced more by Rosuvastatin 10 mg than by milligram equivalent dose of Atorvastatin. But this reduction by Rosuvastatin 10 mg was not statistically different from that seen with Atorvastatin 10 mg. The reduction in triglyceride and total cholesterol were significantly greater statistically with Atorvastatin 10 mg than with Rosuvastatin 10 mg (p<0.05). However increase in HDL-C level was more in case of treatment with Atorvastatin 10 mg than Rosuvastatin 10 mg (p<0.05). [Graph 3.1, 3.2, 3.3, 3.4]
The reduction of LDL-C was greater by Atorvastatin 20 mg than by Rosuvastatin 20 mg (p<0.05). There was seen a statistically significant increase in HDL-C level in case of treatment with Rosuvastatin 20 mg than with Atorvastatin 20 mg (p<0.05). [Graphs 4.1, 4.2, 4.3, 4.4]
Graph 4.1: Comparison of Rosuvastatin 20 mg vs. Atorvastatin 20 mg in Lowering LDL-C Level

Graph 4.2: Comparison of Rosuvastatin 20 mg vs. Atorvastatin 20 mg in Lowering Triglyceride Level

Graph 4.3: Comparison of Rosuvastatin 20 mg vs. Atorvastatin 20 mg in Lowering Total Cholesterol Level
Comparison of safety between Atorvastatin (10 mg, 20 mg) and Rosuvastatin (10 mg, 20 mg)

Both the statins at 10 mg dose did not produce any increase in liver enzyme level at the end of 12 weeks. But 3 patients taking Atorvastatin 20 mg showed an increase in SGPT and SGOT levels whereas no such increase in liver enzyme levels and creatinine kinase elevations were found in patients taking Rosuvastatin 20 mg (p<0.05). [Graphs 5.1,5.2,5.3,5.4]
Graph 5.2: Comparative Analysis of effect on SGOT Level after treatment with Rosuvastatin (10mg), Atorvastatin (10mg)

Graph 5.3: Comparative Analysis of effect on SGPT Level after treatment with Rosuvastatin (20mg), Atorvastatin (20mg)

Graph 5.4: Comparative Analysis of effect on SGOT Level after treatment with Rosuvastatin (20mg), Atorvastatin (20mg)
DISCUSSION
This study evaluated the comparative efficacy and safety of Rosuvastatin (10mg, 20 mg) versus Salveo Andaman Noni in East Indian patients with dyslipidaemia. In this study LDL-C, TG, TC levels were reduced more by statin than by Salveo Andaman Noni. But patients treated with Salveo Andaman Noni (freeze dried) showed significant reduction in LDL-C, TG, TC levels. However, HDL cholesterol level increased significantly more by Salveo Andaman Noni than by Rosuvastatin 10 mg, Atorvastatin 10 mg and Atorvastatin 20 mg. The oxidative modification of low density lipoprotein (LDL) plays an important role in the genesis of arteriosclerosis. Thus our study substantiates a previous study by Kamiya et al, that Salveo Andaman Noni (freeze dried) appears to be cardioprotective by reducing risk of arteriosclerosis. This study demonstrated that Salveo Andaman Noni (freeze dried) not only regulates serum lipid levels by lowering the total cholesterol, triglyceride, low density lipoprotein levels but also restores the cardioprotective high density lipoprotein level.

In case of comparative safety analysis it was seen that patients treated with Atorvastatin 20 mg had higher serum SGPT and SGOT levels which in long term may lead to liver dysfunction. Whereas, liver enzyme levels of patients with Salveo Andaman Noni (freeze dried) were in the normal range.

Thus we can suggest that patients suffering from dyslipidaemia who are undergoing statin treatment to achieve the normal lipid levels can have Salveo Andaman Noni along with low dosage of statin to reduce the risk of liver dysfunction in their long term of treatment regimen. Previous studies also substantiates that Salveo Andaman Noni also reduces platelet aggregation and the sensitivity of the heart to adrenergic stimulation and improves the contractility of the heart by executing positive inotropic action. It increases the inotropic action by 25%, whereas both Rosuvastatin and Atorvastatin has no such effect.

In results of our study in comparative effect of Rosuvastatin with Atorvastatin in patients with dyslipidaemia revealed that Rosuvastatin 10 mg was more effective in reducing LDL-C than atorvastatin 10 mg. But Atorvastatin 10 mg was more efficacious in reducing TG and TC levels in the patients than equivalent milligram dose of Rosuvastatin 10 mg. However increase in HDL- C level was more in case of treatment with Atorvastatin 10 mg than Rosuvastatin 10 mg (p<0.05). At 20 mg dose of both statins, Atorvastatin was more efficacious in significantly lowering LDL- C. Triglyceride level and total cholesterol were significantly reduced by Rosuvastatin 20 mg than Atorvastatin 20 mg. There was seen a statistically significant increase in HDL-C level in case of treatment with Rosuvastatin 20 mg than with Atorvastatin 20 mg.

In this study we have also compared the effect of Rosuvastatin (10 mg, 20 mg) with
Atorvastatin (10 mg, 20 mg) on liver enzymes (SGOT, SGPT) levels. This study showed that 3 patients out of total patients treated with Atorvastatin 20mg had increased level of SGOT and SGPT. There were no serious adverse events reported in this study. The biochemical markers that are widely used in the detection of infraction are CK, a more sensitive and cardio specific isoform of this enzyme was CK-MB. Our study revealed that Rosuvastatin reduced CK levels when compared to Atorvastatin. These results might be of value to practising physicians while selecting suitable statins for the patients in East Indian population.

REFERENCES
14. Maiden JH. Useful native plants of Australia including Tasmania. Sydney: Tuner and Henderson Publisher; 1889;45
18. Solomon N. The tropical fruit with 101 medicinal uses, NONI juice. 2nd ed. Woodland Publishing; 1999
20. Salley MN, Runniel I and Roach PD. Inhibition of low-density lipoprotein


24. Michael B Clearfield, John Amerena, Jean-Pierre Bassand, Hugo R Hernández García, Sam S Miller, Froukje FM Sosef, Michael K Palmer and Brian S Bryzinski. Comparison of the efficacy and safety of rosvastatin 10 mg and atorvastatin 20 mg in high-risk patients with hypercholesterolemia – Prospective study to evaluate the Use of Low doses of the Statins Atorvastatin and Rosuvastatin (PULSAR): Trials 2006;7:35.