Discussion
DISCUSSION

This work was conducted in the department of Medicine, M.L.B. Medical College, Jhansi on patients suffering from systemic hypertension, Diabetes Mellitus, Ischemic Heart Disease, Myocardial Infarction or Nephrotic syndrome having hypercholesterolemia (>200mg/dl), hypertriglyceridemia (>200mg/dl) or both.

The Changes in Serum total cholesterol (STC): 

The values obtained were compared with the basal values.

Group A (Raw garlic group):

The mean basal fasting values of the patients in this group was 223.2±28.45 while the values after 4 and 12 weeks of treatment and after 3 months of withdrawal are 208.4±27.08, 197.8±11.76, 211.0±17.52 respectively, while the percentage decrease from the mean basal values are 6.74%, 9.43% and 3.05% respectively.

Group B (Garlic pearls group):

The mean basal fasting values of the patients in this group was 211.8±21.48 while the values after 4 and 12 weeks of treatment and after 3 months of withdrawal are 201.1±19.49, 191±15.50, 201.3±11.55 respectively while the percentage decrease from the
mean basal values are 4.99%, 7.74%, 3.02% respectively. Two subjects after 3 months of withdrawal have even showed an increase in STC from basal value i.e. average 4%.

**Group C (Simvastatin Group):**

The mean basal fasting values of STC of the patients in this group was 208±10.45. The values after 4 and 12 weeks of treatment and after 3 month of withdrawal are 198±9.8, 184.6±12.24, 202.6±21.11 respectively while the percentage decrease from mean basal values are 6.06% (In 2 subjects no change is observed), 11.21%, 6.96% (In 2 subjects values increase more than basal value by an average of 14.25%) respectively.

On statistical analysis we found that the serum cholesterol lowering effect of raw garlic and garlic pearls were statistically insignificant (P>0.05 in both groups) but the cholesterol lowering effect of simvastatin was statistically very significant (P<0.001) after 12 weeks of treatment. After 3 months of withdrawal cholesterol lowering effect in all the three groups was insignificant.

**The Changes in Serum triglyceride (STG):**

**Group A (Raw garlic group):**

The mean basal fasting values of STG of patients in this group was 180.6±79.40. The values after 4 and 12 weeks of treatment and
after 3 months of withdrawal are 171.5±64.06, 149.2±59.52, 161.2±67.67 respectively while the percentage decrease from mean basal values are 10.05%, 20.58%, 10.86% respectively. Although 2 patients in this group showed an increase in STG levels by 10.15%, 2.0% and 10.7% respectively.

**Group B (Garlic pearls group)**

The mean basal fasting value of STG of patients in this group was 169.8±47.71 while the values after 4 and 12 weeks of treatment and after 3 months of withdrawal are 156.3±44.71, 141.8±33.83, 162.3±41.99 respectively while the percentage decrease from mean basal values are 9.91% (2 subjects showed no change), 18.31% and 14.33% respectively.

**Group C (Simvastatin group):**

The mean basal fasting values of STG of patients in this group was 224.1±88.66 while the value after 4 and 12 weeks of treatment and after 3 months of withdrawal are 196.1±67.19, 163.2±40.10, 158.4±55.30 respectively, while the percentage decrease from the mean basal values are 10.46%, 21.88% and 18.47% respectively.

On statistical analysis lowering of STG by raw garlic (P>0.4) garlic pearls (P>0.2) and of simvastatin (P>0.05) after 12 weeks of
treatment remain insignificant. After 3 months of withdrawal lowering effect of STG remain statistically insignificant.

**The Changes in High density lipoprotein (HDL):**

**Group A (Raw garlic group):**

The mean basal fasting value of HDL in this group was 43.7±7.56 while the values after 4 and 12 weeks of treatment and after 3 months of withdrawal are 43.3±7.47, 41.7±7.20, 41.0±10.22 respectively.

**After 4 weeks** - HDL was decreased by 2.07%. 3 subjects showed no change and one subject showed an increase by 3.8%.

**After 12 weeks** - HDL found to decrease by 2.15%, 2 subjects showed no change and 2 subjects showed 4.3% increase.

**After 3 months of withdrawal** - Subjects showed 2.15% decrease in HDL 3 subjects showed no change.

**Group B (Garlic pearls group):**

The mean basal fasting value of subjects in this group was 43.6±1.87 while after 4 and 12 weeks of treatment and 3 months of withdrawal are 44.5±1.01, 45±1.73, 44.2±0.98 respectively.

**After 4 weeks** - Subjects showed 5.5% increase while 1 subject showed no change and 2 subjects showed fall by 4.4%.
**After 12 weeks** - Subjects showed increase by 6.62%, 2 subjects showed fall by 4.35%.

**After 3 months of withdrawal** - Subjects showed increase by 4.8%, 1 subject showed no change and 2 subjects showed decrease by 3.2%.

**Group C (Simvastatin group):**

The mean basal fasting value of HDL of subjects in this group was 48.2±6.17, while after 4 and 12 weeks of treatment and after 3 months of withdrawal are 48.8±6.66, 50.4±6.14, 47.3±5.38 respectively.

**After 4 weeks** - Subjects showed an increase by 3.29%, 3 subjects showed no change and a fall by 6.6% in 1 subject.

**After 12 weeks** - Subjects showed an increase by 5.28%. No change in one subject.

**After 3 months of withdrawal** - Subjects showed increase by 9.15%, 1 subject no change and in 4 subjects decrease by 3.78%.

On analysis changes in HDL are statistically insignificant in all the three groups, after 4 and 12 weeks of treatment and after 3 months of withdrawal.
The Changes in Very Low Density Lipoprotein (VLDL): 

**Group A (Raw garlic group):**

The mean basal fasting value of VLDL in subjects of this group was 36.1±15.82, while the values after 4 and 12 weeks of treatment and after 3 months of withdrawal are 34.3±12.81, 29.8±11.98, 32.2±13.53 respectively.

**Group B (Garlic Pearls group):**

The mean basal fasting values of the VLDL in subjects of this group was 33.8±9.48, while the values after and 12 weeks of treatment and after 3 months of withdrawal are 31.2±8.98, 28.4±6.88, 32.5±7.10 respectively.

**Group C (Simvastatin group):**

The mean basal fasting values of the VLDL in subjects of this group was 44.8±17.72, while the values after 4 and 12 weeks of treatment and after 3 months of withdrawal are 39.2±13.29, 32.5±8.00, 31.7±12.09 respectively.

On analysis the changes in VLDL i.e. the decrease in all the three groups are statistically insignificant, after 4 and 12 weeks of treatment and after 3 months of withdrawal.
The Changes in LDL (Low Density Lipoprotein):

Group A (Raw Garlic group):

The mean basal fasting value of LDL in subjects of this group was 143.3±21.53, while the values after 4 and 12 weeks of treatment and after 3 months of withdrawal are 131.5±18.13, 126.4±13.24, 137.8±18.35 respectively.

After 4 weeks subjects showed decrease by 8.75% except one subject who showed increase by 1.09%.

After 12 weeks subjects showed decrease by 15.87%, in 2 subjects increase by 0.445%.

After 3 months of withdrawal the fall remained to 6.13% and in 2 subjects an increase was noted by 4.0%.

Group B (Garlic Pearls group)

The mean fasting value of LDL in this group was 134.4±30.17, while after 4 and 12 weeks of treatment and after 3 months of withdrawal are 125.4±26.97, 117.6±21.87, 124.6±18.76 respectively.

After 4 weeks of treatment - Subjects showed a fall by 7.36%, in 1 subject an increase by 0.97% was noted.
**After 12 weeks of treatment** - Fall by 9.55%, in 1 subject an increase by 0.97% was noted.

**After 3 months of withdrawal** - Only 2 subjects showed a fall by 4.85%, rest of the subjects showed a rise by 6.65%.

**Group C (Simvastatin group)**

The mean basal fasting value of LDL of subjects in this group was 115.9±19.99, while after 4 weeks and 12 weeks of treatment and after 3 months of withdrawal are 109.8±15.39, 101.7±17.28, 123.6±30.58 respectively.

**After 4 weeks of treatment** - LDL decreased by 11.29% in 5 subjects and 4.38% increase was noted in 4 subjects.

**After 12 weeks of treatment** – Decrease of 13.81% was noted, in 1 subject increase by 5.5% was noted.

**After 3 months of withdrawal** - LDL fall of 13.05% was noted, 1 subject showed no change and 3 subjects showed an average increase of 26.3%.

On statistical analysis the changes in LDL i.e. the lowering effect of LDL in all the three groups was statistically insignificant, after 4 and 12 weeks of treatment. Values remain insignificant after 3 months of withdrawal.
The present study does not substantiate the lipid lowering effect of raw garlic or garlic pearls as lowering of serum total cholesterol is statistically insignificant.

A study conducted by Arora RC, Arora S et al (1981) at the Department of Medicine, M.L.B. Medical College, Jhansi; substantiated the similar conclusion that the STC rise after fat intake was not prevented by intake of garlic. Their published data indicated that garlic had no effect of STC\textsuperscript{1}.

A similar study conducted by Arora RC, Arora S, Gupta RK et al at M.L.B. Medical College and Hospital, Jhansi i.e. "The long term use of garlic in ischemic heart disease" showed marginal fluctuation in STC after garlic pearls. Statistical analysis of their mean gave insignificant P values\textsuperscript{6}.

The present study has shown that few subjects while on raw garlic revealed an increase of serum triglyceride instead of a fall.

We know that increase carbohydrate in diet lead to increase in plasma triglyceride levels. It may have been possible that when we tried to restrict subjects on routine diets not rich in fat and cholesterol some subjects may have increased carbohydrate in their diet hence result we found were inconsistent.
Secondly study conducted by Arora RC, Arora S, Gupta RK, et al\(^6\) showed in their published data the levels STG have risen twice during the period of garlic use from the mean basal values. Statistical analysis were found to be insignificant which is similar to the present study.

Thirdly meta- analysis by Neil, CA Silagy\(^{33}\) had shown that TG levels ranges from (1.24-2.10 mmol/L) at baseline to (0.94-2.34 mmol/L) after garlic therapy. Henceforth it reveals that STG had raised in few subjects.

Fourthly Steiner, et al\(^{32}\) had reported that there was a transient elevations in total cholesterol and triacylglycerol concentrations during initial supplementation this was later followed by a significant reduction below baseline levels.

In our study we found no statistically significant change in the level of HDL. Few subjects showed a decrease in HDL levels, while on raw garlic or garlic pearls.

A study showed that large intake of carbohydrates lead to increase in triglyceride levels and decrease in HDL levels. As Indians consume large carbohydrate diet and that would be the cause of fall of HDL level.
Meta-analysis of Neil, CA Silagy had shown an insignificant rise of HDL, $1.14\pm0.27$ mmol/L to $1.21\pm0.30$ mmol/L, similar to the present study.

In present study LDL showed inconsistent results with statistically insignificant fall with increase in few subjects while on raw garlic or garlic pearls.

Similar results of increase in LDL level and insignificant P value was shown by Arora RC, Arora S, Gupta RK et al.

A large meta-analysis conducted by Neil, CA Silagy, T Lancaster, J Hodgeman et al published in the Journal of the Royal College of Physicians of London Vol 30, No-4, 1996 had shown that levels of LDL had increased after garlic therapy from $5.08\pm0.56$ to $5.14\pm0.69$ mmol/L.

As one subject in present study had shown a rise in LDL after 4 weeks and then a fall. Steiner, et al had reported that there was a transient elevation of STC, STG and the ratio of LDL to very low density lipoprotein followed by a fall while on garlic therapy.

Similar to the present study, Leon A, Simon et al concluded in his study that garlic powder tablets appeared to have no significant effect on lipid lipoprotein profile.
The present study concluded that the cholesterol lowering effect of simvastatin is very significant (p<0.001) which is similar to the 4S study\textsuperscript{50} conducted on simvastatin.

Lowering of STG by simvastatin is 21.88\% in present study after 12 weeks of treatment which is within the range of drop of STG by statins in the report published by NCEP Adult treatment Panel-III\textsuperscript{61}.

Increase in HDL by simvastatin was found to be 5.248\% which is within the range of HDL increase by statins as published in the report of NCEP-Adult treatment Panel-III\textsuperscript{61}. Fall shows by one subject has an explanation similar to the above as in raw garlic and garlic pearls group.

The drop in the LDL level was 13.8\% after 12 weeks of simvastatin therapy lower than the drop shown by NCEP – Adult treatment Panel-III\textsuperscript{61} report and 4S\textsuperscript{50} study group but most of the patients had achieved the goal of LDL <100mg/dl. Remaining subjects could have achieved the goal with higher dose of simvastatin which had not been given to the subjects of the present study.
Fasting values of the three groups i.e. Raw garlic, Garlic pearls and simvastatin at basal, after 12 weeks of treatment and after 3 months of withdrawal are:

<table>
<thead>
<tr>
<th></th>
<th>Raw Garlic Group</th>
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<th>Garlic Pearls Group</th>
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<th>Simvastatin Group</th>
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<tbody>
<tr>
<td></td>
<td>Basal</td>
<td>12 weeks</td>
<td>After 3 months of withdrawal</td>
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<td>12 weeks</td>
<td>After 3 months of withdrawal</td>
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<tr>
<td>STC</td>
<td>223.2± 28.45</td>
<td>197.8± 11.76</td>
<td>211.0± 17.52</td>
<td>211.8± 15.48</td>
<td>191.0± 11.55</td>
<td>201.3± 11.55</td>
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<tr>
<td>STG</td>
<td>180.6± 79.40</td>
<td>149.2± 59.52</td>
<td>161.2± 67.67</td>
<td>169.8± 47.71</td>
<td>141.8± 33.83</td>
<td>162.3± 41.99</td>
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<tr>
<td>HDL</td>
<td>43.7± 7.56</td>
<td>41.7± 7.20</td>
<td>41.0± 10.22</td>
<td>43.6± 1.87</td>
<td>45.0± 1.73</td>
<td>44.2± 0.98</td>
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<tr>
<td>VLDL</td>
<td>36.1± 15.82</td>
<td>29.8± 11.98</td>
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