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***Slavica VUJOVIC*[1,2]*, Svetlana PEROVIC*[1,2]*, Stasa SCEPANOVIC*[4]*, Aleksandra FILIPOVIC*[3]*, Kerim HADZAJLIC*[5]

LIPID PROFILE OF THE ELDERLY IN THE RURAL AREA OF NORTHERN MONTENEGRO

SUMMARY

The aim of this study was to evaluate the effect of simvastatin on the lipid profile of elderly patients with dyslipidemia in real-world clinical settings. This prospective observational study included 80 participants with an average age of 48.5 years, who underwent biochemical testing during July and August 2016 at the General Hospital in Bijelo Polje. Half of the participants (n=40) were treated with simvastatin, while the control group (n=40) did not receive statin therapy. Lipid profile was assessed by measuring total cholesterol and triglycerides using enzymatic methods. Data were analyzed using statistical tests appropriate for non-parametric distributions. Simvastatin therapy showed a favorable trend in lowering blood lipid levels, including total cholesterol and triglycerides, although differences compared to the control group were not statistically significant. Age did not significantly influence therapeutic response, highlighting the need for individualized treatment strategies based on additional factors. Simvastatin is effective in improving lipid profiles in elderly patients with dyslipidemia. However, more extensive studies with longer follow-up and incorporation of genetic and clinical parameters are required for definitive conclusions. An individualized approach to dyslipidemia management remains a challenge in contemporary cardiovascular therapy.

Keywords: lipid profile, dyslipidemia, elderly population, rural area, therapeutic response.

INTRODUCTION

Cardiovascular diseases (CVDs) remain the leading cause of mortality worldwide, with dyslipidemia recognized as one of the key modifiable risk

[1]Slavica Vujovic [*](corresponding author:: slavica.v@ucg.ac.me), University of Montenegro, Faculty of Natural Sciences and Mathematics, Podgorica, MONTENEGRO
[2]Svetlana Perovic, University of Montenegro, Faculty of Medicine, Podgorica, MONTENEGRO
[3]Aleksandra Filopovic Private Health Centre Polyclinic Filipovic, Podgorica, MONTENEGRO
[4]Stasa Scepanovic Clinic of Gynecology and Obstetrics, University Clinic Centre of Serbia, University of Belgrade, Faculty of Medicine, Belgrade, SERBIA
[5]Kerim Hadzajlic, Private Hospital Codra, Podgorica, MONTENEGRO
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factors. Elevated levels of total cholesterol and triglycerides significantly contribute to the development of atherosclerotic changes, including hypertension, myocardial infarction, and various forms of heart failure (Mach *et al.,* 2020). Timely identification of patients with dyslipidemia and implementation of appropriate therapeutic interventions—whether through dietary modification or pharmacological treatment with statins—plays a crucial role in the prevention of these conditions. Statins, such as simvastatin, are HMG-CoA reductase inhibitors and constitute the cornerstone of contemporary dyslipidemia therapy. They reduce hepatic cholesterol synthesis, which leads to upregulation of LDL receptors and enhanced clearance of LDL particles from the circulation (Liao & Laufs, 2005). Clinical trials have demonstrated that statins can lower total cholesterol levels by approximately 30–40 mg/dL, and triglyceride levels by about 10–20 mg/dL (Aslani *et al*., 2023; Xiang *et al.,* 2025). Moreover, recent meta-analyses confirm a significant effect of statins in reducing all-cause mortality and the incidence of major cardiovascular events, particularly among high-risk populations (Navarese *et al.*, 2024).

Despite their proven efficacy, the therapeutic response to statins varies considerably among individuals. Factors such as age, sex, comorbidities, and especially genetic predispositions substantially influence treatment outcomes (Santos *et al*., 2016; Asiimwe *et al*., 2024). Studies have shown that younger patients often exhibit a more favorable response, whereas older individuals may require dose adjustments due to increased susceptibility to adverse effects (Asiimwe *et al*., 2024). Of particular interest is the apolipoprotein E (APOE) genotype, which has been associated with differential responses to statin therapy and variations in metabolic sensitivity (Kullo & Fan, 2010; Asiimwe *et al*., 2024). Additionally, the role of pharmacogenetics in optimizing lipid-lowering therapy is increasingly being explored, with the identification of polymorphisms that may predict statin efficacy and safety (DeGorter *et al*., 2023).

Beyond pharmacological interventions, nutrition remains a critical component in lipid profile management. Evidence supports that diets rich in unsaturated fats, fiber, and antioxidants—such as the Mediterranean dietary pattern—can contribute to further reductions in total cholesterol and triglyceride levels (Estruch *et al*., 2013; Schwingshackl & Hoffmann, 2014; Šćepanović *et al*., 2024). Recent studies emphasize the potential benefits of incorporating fermented dairy products, omega-3 fatty acids, and plant sterols as adjuncts to pharmacotherapy (Chen *et al*., 2023; Mehta *et al.*, 2025).

Emerging therapeutic strategies include combination regimens, such as statins with ezetimibe or CETP inhibitors, which have demonstrated greater efficacy in lowering LDL cholesterol without significantly increasing the risk of adverse events (Sydhom *et al*., 2024; Xiang *et al.,* 2025). Furthermore, novel drug classes are under development—including PCSK9 inhibitors, RNA interference therapies, and bempedoic acid—offering promising options for patients with statin intolerance or treatment-resistant dyslipidemia (Sabatine *et al.,* 2023; Laufs *et al*., 2024). A personalized approach that integrates genetic

profiling, biomarker monitoring, and individualized treatment regimens is increasingly recognized as essential in modern cardiometabolic medicine.

The aim of this study is to assess the effect of simvastatin therapy on lipid parameters—namely total cholesterol and triglyceride levels—among patients in the General Hospital in Bijelo Polje. Special attention is given to evaluating the efficacy and tolerability of simvastatin across different age groups and between sexes, with a view to understanding the real-world therapeutic outcomes in a primarycare setting.

This research holds particular significance for the rural population of northern Montenegro**,** where cardiovascular morbidity remains high and access to specialized care is limited. By analyzing the local response to standard statin therapy, the study aims to provide evidence-based recommendations for improving dyslipidemia management in under-resourced regions and inform future strategies for primary prevention of cardiovascular disease in similar rural contexts.

MATERIAL AND METHODS

Participants

This prospective observational study included a total of 80 patients undergoing routine biochemical monitoring at the General Hospital of Bijelo Polje, Municipality at north of Montenegro (Figure 1). The research was conducted over a six-month period, from May to October 2023. Among the participants, 40 patients receiving Hollesta (simvastatin) therapy formed the experimental group, while the remaining 40 patients, who were not using statins, comprised the control group. Out of the total number of participants, 31 (38.75%) were female and 49 (61.25%) were male. The mean age in both groups was 48.5 years.

All participants provided written informed consent prior to inclusion in the study, which was conducted in accordance with the ethical principles of medical research.

Biochemical MethodsDetermination of Total Cholesterol (CHOD-PAP method): Analyses were performed using the Alfa Wassermann ACE Alera automated biochemistry analyzer, applying the enzymatic colorimetric CHOD-PAP method. Serum or plasma samples (EDTA/heparin) were used. The method is based on the oxidation of free cholesterol with the formation of hydrogen peroxide, which then reacts with phenol and 4-aminoantipyrine in the presence of peroxidase, yielding a colored quinoneimine chromogen. Absorbance was measured at 500 nm.

Figure 1. Administrative and geographic context of the study area in northern Montenegro: Bijelo Polje Municipality within Montenegro (highlighted in red).

Reference values:

- Normal: < 5.2 mmol/L
- Moderate risk: 5.2–6.19 mmol/L
- High risk: > 6.2 mmol/L

Determination of Triglycerides (GPO-PAP method): Triglyceride levels were measured by an enzymatic method based on the quantification of hydrogen peroxide generated through the oxidation of glycerol-3-phosphate. The reagents used contained lipase, glycerol kinase, GPO, and POD. The intensity of the resulting color was proportional to the triglyceride concentration. Absorbance was measured at 500 nm.

Reference values:

- Optimal: < 1.7 mmol/L
- Borderline: 1.7–2.25 mmol/L
- High: 2.26–5.64 mmol/L
- Very high: > 5.65 mmol/L

Characteristics of the Investigated Drug – Hollesta (Simvastatin): Hollesta is a lipid-lowering agent from the statin group (HMG-CoA reductase inhibitors). It is administered orally in doses ranging from 5 to 80 mg once daily in the evening. The initial recommended dose is 10–20 mg per day, while doses up to 80 mg may be used in severe hypercholesterolemia. Treatment is accompanied by a standard lipid-lowering diet. Hollesta is contraindicated during pregnancy, lactation, active liver disease, and in combination with gemfibrozil, cyclosporine, ordanazol.

Statistical Analysis

Data were analyzed using SPSS software version 24.0 for Windows. Quantitative variables were presented as arithmetic means, standard deviations, and 95% confidence intervals. Due to non-normal distribution of data, the Mann–Whitney U test was applied to compare the experimental and control groups. The correlation between age and biochemical parameters was assessed using Pearson's correlation coefficient. Statistical significance was defined as $p < 0.05$.

RESULTS

Biochemical Marker Levels in the Experimental and Control Groups

The arithmetic means, standard deviations, and 95% confidence intervals for the studied variables (cholesterol and triglyceride levels) are presented in Table 1. Statistical significance was also assessed between the experimental and control groups.

Table 1. Biochemical Parameters in the Experimental and Control Groups

Variable	Experimental Group	Control Group	p-Values
Cholesterol	4.61 ± 0.16 (range: 0–5.2)	5.07 ± 0.12	0.260 / 0.031*
Triglycerides	1.66 ± 0.66 (range: 0–2.26)	1.63 ± 0.75	0.478 / -0.009*

The mean cholesterol level in the experimental group was 4.61 ± 0.16 (95% CI: 0–5.2), while in the control group it was 5.07 ± 0.12 (95% CI: 0–5.2). The median serum cholesterol level was higher in the group not receiving Hollesta therapy compared to the group receiving it; however, this difference was not statistically significant.

The mean triglyceride level in the experimental group was 1.66 ± 0.66 (95% CI: 0–2.26), compared to 1.63 ± 0.75 (95% CI: 0–2.26) in the control group. The median triglyceride level was higher in the experimental group than in the control group, but again, the difference was not statistically significant.

Pearson correlation analysis showed that in the control group, the correlation between age and cholesterol level was 0.03, indicating a weak relationship. In the experimental group, the correlation was 0.25, suggesting a slight association. The correlation between triglyceride levels and age was weak in both groups.

Influence of Age on Biochemical Markers

The Mann–Whitney U test did not reveal significant differences in serum cholesterol levels between the experimental and control groups for any age subgroup. Specifically:

- In the 37–40 age group (N=9), U=3.000, Z=–1.006, p=0.314
- In the 40–45 group (N=8), U=3.000, Z=0.000, p=1.000
- In the 45–50 group (N=7), U=1.000, Z=–1.464, p=0.143
- In the 50–55 group (N=8), U=3.000, Z=–1.342, p=0.180
- In the 55–60 group (N=8), U=5.000, Z=–0.745, p=0.456

No significant differences were observed for serum triglyceride levels either:

- 37–40 group (N=9), U=5.000, Z=–0.333, p=0.739
- 40–45 group (N=8), U=1.000, Z=–1.000, p=0.317
- 45–50 group (N=7), U=2.000, Z=–0.293, p=0.770
- 50–55 group (N=8), U=4.000, Z=–1.043, p=0.292
- 55–60 group (N=8), U=7.000, Z=–0.149, p=0.331

Table 2. Comparison of Biochemical Parameters in Different Age Subgroups

Biochemical Parameter	Age Group	N	U	z	p
Cholesterol	37–40	9	3.000	–1.006	0.314
	40–45	8	3.000	0.000	1.000
	45–50	7	1.000	–1.464	0.143
	50–55	8	3.000	–1.342	0.180
	55–60	8	5.000	–0.745	0.456
Triglycerides	37–40	9	5.000	–0.333	0.739
	40–45	8	1.000	–1.000	0.317
	45–50	7	2.000	–0.293	0.770
	50–55	8	4.000	–1.043	0.293
	55–60	8	7.000	–0.149	0.331

Note: N – sample size; U – Mann–Whitney U statistic; z – standardized value; p – statistical significance

Serum Cholesterol Concentrations by Age Group

The average cholesterol concentrations in both the experimental and control groups by age are presented in Figures 2 and 3. The highest average cholesterol levels were found in the 50–55 age group in both study arms. The lowest mean cholesterol value was observed in the 40–45 age group in the experimental group, suggesting that Hollesta may be most effective in this subgroup. Conversely, the highest average cholesterol in the experimental group was also seen in the 50–55 subgroup, possibly indicating poor adherence to prescribed therapy and dietary/exercise recommendations.

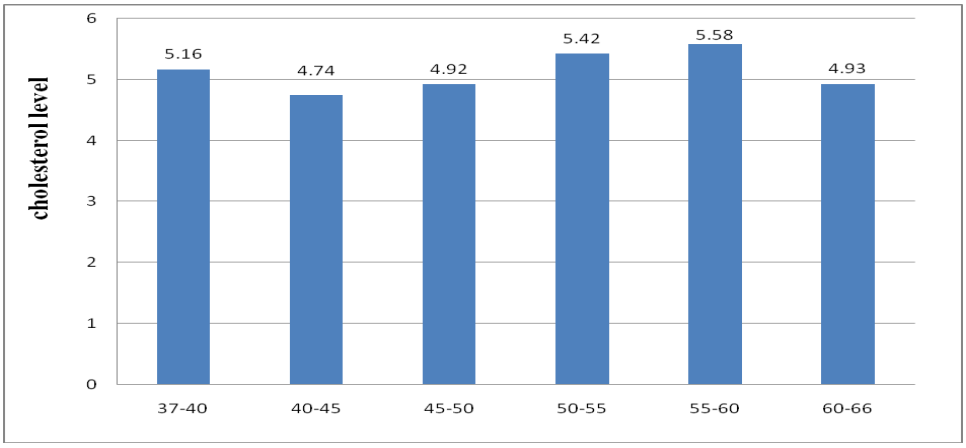

Figure 2. Mean Serum Cholesterol Levels by Age Group – Control Group

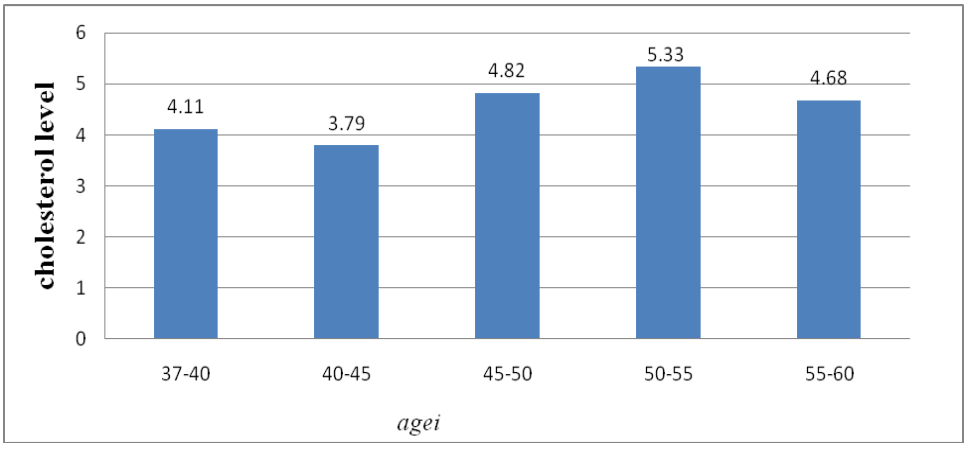

Figure 3. Mean Serum Cholesterol Levels by Age Group – Experimental Group

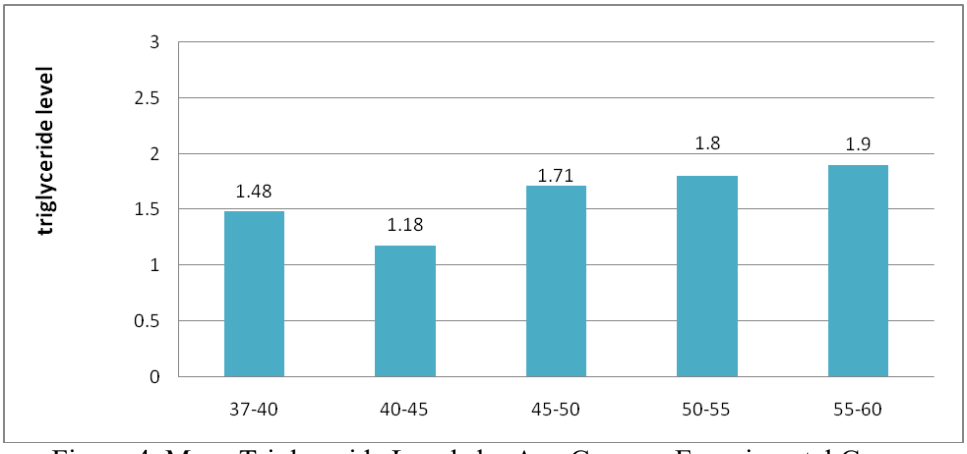

Figure 4. Mean Triglyceride Levels by Age Group – Experimental Group

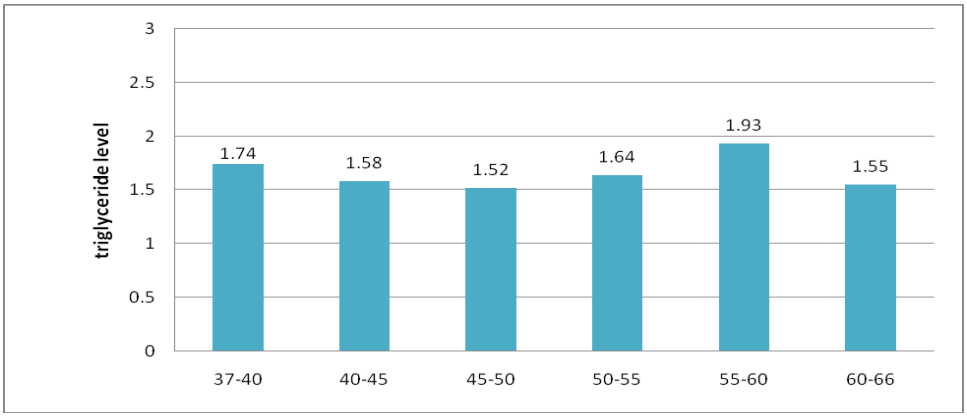

Figure 5. Mean Triglyceride Levels by Age Group – Control Group

Serum Triglyceride Concentrations by Age Group

Figures 4 and 5 show the mean triglyceride levels in both groups. The highest average triglyceride concentration in the experimental group was observed in the 55–60 age group, while the lowest was in the 40–45 age group. A similar pattern was seen in the control group: the 55–60 age group had the highest average, and the 40–45 group the lowest.

DISCUSSION

The findings of our study suggest that the administration of simvastatin (Hollesta) in patients treated at the General Hospital Bijelo Polje resulted in a reduction in total cholesterol and triglyceride levels within the experimental group, although these reductions did not reach statistical significance. This trend aligns with results from recent meta-analyses confirming the lipid-lowering efficacy of statins across diverse patient populations. For instance, a 2023 meta-analysis reported that statins significantly reduced total cholesterol (WMD −33.37 mg/dL) and triglycerides (WMD −15.19 mg/dL) (Aslani *et al*., 2023).

Our findings are consistent with the broader literature. A large-scale prospective meta-analysis pooling data from over 90,000 participants across 14 randomized trials demonstrated that lowering LDL-C by 1 mmol/L (≈38.7 mg/dL) corresponds to a 20% reduction in major cardiovascular events (Baigent *et al*., 2005). The ASCOT-LLA study further supports these findings, revealing that atorvastatin significantly reduced the incidence of myocardial infarction and stroke in hypertensive patients, independent of baseline cholesterol levels (Sever *et al.,* 2003).

While our study utilized simvastatin monotherapy, recent evidence supports more potent lipid-lowering effects through combination therapies. A systematic review from 2024 found that the addition of ezetimibe to simvastatin provides superior reductions in LDL-C and triglycerides compared to monotherapy (Sydhom *et al*., 2024). Furthermore, Xiang *et al*. (2025) reported that the combination of statins with CETP inhibitors yields even greater lipid-

lowering benefits, particularly in high-risk populations, without a substantial increase in adverse events. These observations are further corroborated by the FOURIER trial, where PCSK9 inhibitors combined with statins significantly reduced cardiovascular risk in patients with established atherosclerotic disease (Sabatine *et al., 2*017).

The absence of a statistically significant difference in our study may be explained by the limited sample size, relatively short treatment duration, and potentially variable adherence among participants. Notably, our patient population originates from a rural area in northern Montenegro, where specific lifestyle and dietary patterns—such as higher intake of saturated fats, lower dietary diversity, and irregular access to healthcare—may influence baseline lipid profiles and therapeutic response.

Age did not significantly correlate with changes in lipid parameters in our cohort, which is consistent with previous studies suggesting that genetic factors, particularly APOE genotype, may be more predictive of therapeutic response. A 2024 meta-analysis showed that carriers of the APOE ε4 allele exhibit a blunted response to statin therapy compared to ε2 carriers (Asiimwe *et al*., 2024). Similarly, Stroes *et al*. (2015) noted that although younger patients often respond better to statins, older individuals may require tailored dosing strategies due to altered pharmacokinetics and increased susceptibility to adverse events.

In our sample, the Pearson correlation between age and lipid profile changes was weak ($r < 0.3$), reinforcing the notion that age alone is not a strong determinant of response. These results mirror those of Aslani *et al*. (2023) and Sydhom *et al*. (2024), who also reported minimal age-related differences. Interestingly, the JUPITER trial demonstrated that even individuals with normal LDL-C but elevated high-sensitivity C-reactive protein (hsCRP) may benefit from statin therapy, highlighting the pleiotropic effects of statins, including anti-inflammatory and endothelial-stabilizing properties (Ridker *et al*., 2008).

Additionally, recent data suggest that statin efficacy may be modulated by baseline inflammatory status and metabolic profile. For example, a 2023 study by Liao et al. found that individuals with metabolic syndrome exhibited a more pronounced triglyceride-lowering response to statins, potentially due to concurrent improvement in insulin sensitivity and endothelial function (Liao *et al.*, 2023). Such findings may have implications for our rural cohort, where undiagnosed metabolic syndrome may be prevalent due to low screening rates.

In summary, while our study did not yield statistically significant differences, the observed trends are consistent with established evidence supporting statin efficacy. Future studies with larger sample sizes, longer follow-up periods, assessment of inflammatory biomarkers, and genetic profiling-particularly in underserved rural populations are essential to optimize lipid-lowering strategies and personalize cardiovascular risk reduction.Ministry of Agriculture, General Secretariat of Forests and Natural Environment (1992): The results of the First National Forest Inventory (NFI) of Greece. Independent Edition, Greece. (in Greek)

CONCLUSION

Simvastatin demonstrated a clinically relevant reduction in total cholesterol and triglyceride levels, consistent with findings from contemporary literature. Although the effects on the lipid profile were more pronounced in the experimental group, the difference compared to the control group did not reach statistical significance, likely due to limitations such as the small sample size and short treatment duration. Recent studies increasingly support the use of combination therapies—such as statins with ezetimibe or CETP inhibitors—as more effective approaches for achieving optimal LDL cholesterol and triglyceride levels.

In our sample, age did not significantly influence the therapeutic response, aligning with growing evidence that genetic factors—particularly apolipoprotein E (APOE) status—play a more substantial role in individual sensitivity to lipid-lowering therapy.

Importantly, this study was conducted in a rural population from northern Montenegro, where lifestyle, dietary habits, and access to healthcare services may differ from urban settings. Traditional dietary patterns, physical activity associated with agrarian living, and limited health education and access to consistent treatment could all influence both adherence and response to therapy. These contextual factors must be considered when interpreting the results.

Based on these findings, further research is warranted with larger and more diverse study populations, extended follow-up periods, improved adherence monitoring, and the inclusion of genetic stratification. This would allow for a more accurate assessment of the efficacy and individual variability in response to statin therapy, particularly in underserved rural populations such as those in northern Montenegro.

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