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Efficacy and Safety of Lipid-Lowering Drugs as Primary and Secondary Prevention of Cardiovascular Diseases in the Elderlyin the Uzbekistan

Sharipova Elvina Midkhatovna
Bukhara State Medical Institute, Bukhara, Uzbekistan

ABSTRACT

Management Cardiovascular diseases (CVD) are the leading cause of death worldwide. It is predicted that by 2030 .the number of deaths due to CVD will increase to 23.3 million per year [1]. The prevalence of CVD and its risk factors increases as the population's life expectancy increases [2]. According to the American Heart and Stroke Associations (American Heart Association and American Stroke Association), coronary heart disease (CHD), heart failure, stroke, hypertension, or a combination of these diseases occur in 69.1% of men and 67.9% of women aged 60-79 years and 84.7% and 85.9% over 80 years, respectively [3]. The first heart attack develops on average at the age of 65.0 years in men and 71.8 years in women, and is mainly associated with the presence of atherosclerotic lesions of the coronary bed [3]. The vast majority (about 80%) of people dying from CVD associated with atherosclerosis are people over the age of 65 [4]. In France, people aged 85 years and older account for 43% of deaths from CHD, and 49% from stroke [5]. The effect of hyperlipidemia on morbidity and mortality in elderly patients is considered. The article also highlights the effectiveness and safety of lipid-lowering agents in the primary and secondary prevention of cardiovascular diseases in patients ≥80 years of age, which are the fastest growing population group and have the highest cardiovascular risk. It emphasizes the need to take into account polymorbidity and polypharmacy of risk-increasing adverse reactions caused by both statins themselves and their drug interactions, which requires an assessment of the risk/benefit ratio. In addition, it is necessary to develop reliable tools for predicting relevant outcomes (for example, stroke, disability, reduced quality of life) and evaluating the rationality of lipid-lowering therapy in elderly patients, as well as their adherence to treatment.

KEYWORDS: elderly, hypercholesterolemia, lipid-lowering therapy.

One of the most important risk factors for cardiovascular morbidity and mortality in middle-aged and "young" elderly people (up to 70 years) However, its role in morbidity and mortality of the "oldest" people continues to be debated [7].

Effect of hyperlipidemia on morbidity and mortality in elderly patients Data on the effect of hyperlipidemia on morbidity and mortality in people over 75 years of age are limited and contradictory [7]. In a large observational study, the Copenhagen City Heart Study, involving 4,647 men and 5,829 women aged 40-93 years, the risk of CHD associated with high plasma total cholesterol (TC) decreased with age [8]. The relative risk (RR) of developing CHD was 2.0, 3.1, and 5.1, respectively, in individuals younger than 60 years of age with an OH of 5-6, 6-8, and >8mmol/L. In individuals aged 70-80 years, only a level of OH>8 mmol / l led to an increase in HR to 1.6, and in those aged over 80 years, elevated OH levels were not

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associated with an increased risk of CHD. The results of other observational studies involving the "oldest" patients, which examined the relationship between cholesterol levels and mortality, are presented by Petersen L. K. et al. [7]. A number of studies have shown that at the age of over 70 years, the association between the level of OH and mortality becomes U-shaped, which may be associated with the cumulative effect of comorbidity (for example, chronic inflammation and malnutrition), leading to a decrease in the level of OH in blood serum [2,9]. For example, in a prospective population cohort study involving individuals aged 55-99 years (n=5750), an increase in OH for every 1 mmol/L was associated with a decrease in non-cardiovascular mortality by approximately 12%, and this association reached statistical significance starting from the age of 65 and increased with each subsequent decade [10]. In a meta-analysis of 33 observational studies with a follow-up period of 3 to 32 years, an increase in OH by 1.0 mmol/L resulted in an increased risk of CHD and mortality in men aged 65-79 years. At the same time, in men aged 80 years and older, the level of OH negatively correlated with all-cause mortality, and in women over 65 years of age, there was no significant increase in CHD mortality with an increase in OH level [11]. However, in another meta-analysis of 61 prospective observational studies (approximately 12 million patient-years; 55,000 vascular deaths), OH and low-density lipoprotein (LDL) levels were positively associated with CHD mortality in both middle-aged and elderly patients [12]. However, there was no positive association between the level of OH and stroke mortality, especially in elderly patients and in patients with systolic blood pressure above 145 mm Hg. The risk ratio of vascular mortality in groups of elderly patients began to increase at significantly higher levels of OH than in 40 and 50-year-olds, and this increase was more gradual [12]. A decrease in the level of OH in the oldest individuals leads to a smaller decrease in RR (by about 2%) compared to the youngest (about 15%), but to a significantly greater reduction in absolute risk (AR) – by 128% versus 11%, respectively. Thus, the results of this meta-analysis support lipid-lowering therapy in the "oldest" individuals. However, the benefits of lipid-lowering therapy should be correlated with its safety, especially in the "most elderly", since with age, sensitivity to adverse reactions (HP) of drugs and the consequences of drug interactions, including with drugs used to treat concomitant diseases, increases significantly, the number of which increases with increasing age. Poor hypolipi toleranceAge ECG-Glia СДb AGS Men Women Men Women Men Women 55-64 2,7 1,7 5,5 4,2 26,8 31,5 65-74 3,6 3,2 10,9 7,2 38,0 47,6 75-84 4,2 4,9 13,2 10,2 48,4 59,9 85-94 5,9 9,4 14,2 11,1 47,8 65,6 electrocardiographically information about left ventricular hypertrophy; bСахарный diabetes (treated for diabetes or level of blood glucose ≥200 mg/DL); sartorially hypertension (≥160/95 mm Hg.St.)Hypolipidemic drugs in the elderly demic therapy can have a negative impact on the quality of life, which is of paramount importance for elderly patients, especially those with limited life expectancy. In addition, potential patient adherence to treatment should be evaluated, which largely determines its success. Since all current guidelines for the treatment of hyperlipidemia in the elderly recommend only the use of statins, we will discuss in more detail the safety and efficacy of this pharmacological group.

Safety of statins in elderly patients and adherence to treatment Serious and fatal HP with statin use are rarely reported, but in general, side effects develop in about 10% of patients [13, 14]. The incidence of HP in large clinical trials did not differ between elderly and younger patients, but these studies practically did not involve people over 80 years of age with "fragility" and significant comorbidity [15]. The most common HP in both groups was dyspepsia. The greatest concern with statin treatment is caused by HP on the part of the

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muscles. The frequency of muscle pain and weakness in clinical studies was extremely variable, and in real practice it may differ significantly from that in clinical studies. In the large USAGE study (n=10138), 30% of participants experienced muscle pain [16]. In observational studies, the incidence of myalgia and statin withdrawal due to HP from muscle pain was significantly higher than in RCTs (an average of 2 times), and in elderly patients it was higher than in younger patients [17-20]. It is not clear whether this is due to age-related muscle mass loss, polypharmacy, drug interactions, impaired function of enzymes involved in drug metabolism, or a combination of these factors [21]. Rhabdomyolysis with statins develops at a rate of 1: 10,000, which is about 400 times less common than bleeding with low-dose aspirin [22]. Muscle HP and related neuropathies are usually dose-dependent. Risk factors for their development also include female gender, low height/low body mass index, concomitant administration of fibrates (gemfibrozil>fenofibrate) and other drugs metabolized with cytochrome P450, use during surgery, impaired liver or kidney function, fatty liver disease, hypothyroidism, diabetes mellitus, and high alcohol consumption [23].

Other serious statin disorders requiring monitoring in elderly patients include confusion, renal failure, and hepatotoxicity [23]. A number of studies (TNT, SAGE, PROVE-IT TIMI 22) the use of high doses of statins was associated with a higher rate of increase of indicators of liver function tests in the elderly compared to younger people [24-26], but the abolition of statins due to asymptomatic increase in hepatic transaminases, according to the results of the meta-analysis of 14 RCTS for primary prevention of CVD (n=46262), was observed in 0.4% more often in older than in younger individuals [27]. Available evidence suggests that statin use is associated with a moderate but statistically significant increase in the risk of new cases of diabetes mellitus [28]. The increase in AR of their occurrence according to a meta-analysis of 14 primary prevention studies was 0.5% [95% confidence interval (CI) 0.1-1%; p=0.012], but the outcomes in patients with a newly reported increase in HbA1c levels during RCT did not differ from those in patients without diabetes [27]. It is assumed that the risk of developing myalgia, diabetes mellitus, and liver dysfunction is higher in women than in men, but this requires further research [20]. Data on the effects of statins on cognitive function and the risk of developing and progressing dementia are highly controversial. In some observational studies conducted in Europe, Asia, and North America, statin use was associated with a reduced risk of developing and/or progressing vascular dementia and/or Alzheimer's disease [11,12]. However, in a meta-analysis of 2 RCTs (26,340 participants aged 40-82 years, including 11,610 aged 70 years and older), good quality evidence was obtained that statins do not prevent the development of cognitive dysfunction or dementia in older individuals at risk of vascular disease [13]. Similar data were obtained in another systematic review [24]. On the contrary, according to the US pharmacovigilance authorities, statin use is mainly associated with rare cases of cognitive impairment (memory loss and impairment, forgetfulness, amnesia, confusion) [15]. These disorders are usually mild in nature, are completely reversible after statin withdrawal, and do not lead to the progression of cognitive dysfunction. A causal link between statin use and an increased risk of diabetes and dementia has not been definitively proven, but in 2012, a new study published in the Journal of Clinical Pharmacology found that statin use is associated with increased risk of diabetes and dementia.

The U.S. Food and Drug Administration required the introduction of appropriate warnings in the instructions for use of drugs in this group [26]. In the Prospective Study of Pravastatin in the Elderly at Risk (PROSPER), statin therapy was associated with an increased incidence of

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cancer in a targeted statin study aimed at secondary prevention of CVD in elderly patients [17]. The HPS (Heart Protection Study) study showed a tendency to increase the incidence of non-melanoma skin cancer in the elderly . However, in a meta-analysis that included data from 4,032 patients aged 65-74 years and 885 patients aged 75 years, no significant effect of statins on the incidence of cancer or mortality from them was found [4]. Similar results were obtained in a meta-analysis of 26 RCTs (170,000 participants) for patients of different age groups [9]. Moreover, in recent years, a significant number of studies and systematic reviews have been published in which statin use has been associated with a reduced risk of developing cancersof various localities and mortality from them [20-24], although these studies did not conduct a separate analysis of data from elderly patients. The risk of statin HP, including from muscle disorders, is significantly increased against the background of drug interactions [20,23]. The probability of clinically significant drug interactions is highest when lipophilic statins that are metabolized with the participation of cytochrome P450 isoenzymes (lovastatin, simvastatin, and atorvastatin) are used simultaneously with other drugs that are metabolized with cytochrome P450 (fibrates, amiodarone, erythromycin, diltiazem, antifungal drugs from the group of azole derivatives), as well as with grapefruit juice [23]. HP contributes to a decrease in the adherence of elderly patients to statin therapy, which, according to epidemiological studies, is low, especially in the case of their use as a means of primary prevention [23]. Within the first two years, about 75% of patients stop treatment. In the USAGE study (n=10138), 57% of participants stopped using statins due to HP [16]. An important risk factor for the development of NR and reduced medication adherence in the elderly is of polypharmacy [23], therefore, even in the case when the drug is justified from a theoretical point of view, its use in the composition of multiple therapy is unclear, and therefore it is recommended to avoid assigning an elderly "pill for every ailment" ("a pill for every ill"), and to first consider non-pharmacological treatment [25].

Cognitive impairments, sensory disorders (hearing, vision), certain somatic diseases (for example, arthritis, parkinsonism, CVD), and functional disorders also contribute to reduced treatment adherence [23], which should be taken into account when prescribing lipid-lowering drugs to the elderly.

Efficacy of lipid-lowering drugs when used for primary and secondary prevention in elderly patients 2 targeted studies of PROSPER and HPS were devoted to the study of statins as a means of secondary prevention in elderly patients[27,28]. In the PROSPER study, there was a 20% reduction in CHD mortality ($p = 0.0091$), but there was no overall reduction in cardiovascular mortality due to the tendency to increase mortality from stroke and other CVD [37]. In the HPS study, statin use was associated with a reduction in the incidence of MI, stroke, and the need for revascularization by about a quarter, and when adjusted for treatment adherence – by a third, and prevented these complications in 70100 patients out of a thousand [28]. Long-term follow-up of participants in the PROSPER (8.6 years) and HPS (11 years) trials did not reveal a positive or negative effect of statins on mortality. The results of the analysis of subgroups of elderly patients (mainly 65-75 years old) who participated in large statin studies are presented in Table. 2. Most studies have shown a similar reduction in the RR of death and recurrence of CVD associated with atherosclerosis in elderly and younger patients, but due to a higher baseline risk, the reduction in AR in the elderly was greater (up to 2 times)than in middle-aged people [19,]. Thus, the number of patients who need to be treated with statins in order to prevent 1 atherosclerotic event and 1 death (NNT) was significantly lower in the elderly than in the younger ones. In a meta-analysis of data from

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19569 participants in 9 RCTs aged 65-82 years, statin use for secondary prevention of CVD was associated with a 22% and 3.1% reduction in RR and AR all – cause mortality, respectively, 30% and 2.6% in CHD mortality, 26% and 2.3% in non – fatal MI, 25% and 1.7% in stroke, respectively, and a 30% reduction in RR revascularization (AR not reported) [8]. Similar results were obtained in a meta -analysis of data from participants in 26 RCTs [9]. Among the 170,000 patients included in this meta-analysis, 4,032 participants were 65-74 years old and 885 patients were 75 years old. The RR of occlusive vascular events in these age groups was 0.78 (95% CI 0.740.83) and 0.84 (95% CI 0.73-0.97), respectively. No targeted RCTs have been conducted to study the effectiveness of statins as secondary CVD prevention drugs in individuals over 80 years of age. In a cohort study involving 7,220 individuals with severe coronary artery atherosclerosis (≥70%), statin use was associated with a reduction in mortality in all groups of elderly patients (Thus, the effectiveness of statins as a means of secondary prevention of CVD in people under 75 years of age It is confirmed by the results of adequate studies and their meta-analyses. According to the START criteria developed by European experts for elderly patients based on an analysis of evidence-based data, statins are recommended for elderly people with CHD, cerebral or peripheral vascular disease if the patient has no restrictions on daily activity and the life expectancy exceeds 5 years [8]. Recommendations for the use of statins as drugs for secondary prevention of CVD are summarized in Table. 3. The benefits of using fibrates in elderly patients could not be demonstrated in any single study [2]. The role of niacin in secondary prevention of CVD after early completion of the AIMHIGH (Atherothrombosis Intervention in Metabolic Syndrome with Low HDL-C/High Triglycerides: Impact on Global Health Outcomes) study [64] is questioned [15]. A useful adjunct to the treatment of elderly CVD patients who are not tolerating statins or who have if they do not reach the target LDL cholesterol level when used at the maximum dose, ezetimibe may be used. The benefits of adding ezetimibe to a statin are most pronounced in patients with diabetes mellitus and in those aged 75 years and older The tolerability of ezetimibe in older individuals does not differ from that in younger Data on the use of statins as primary prevention drugs for CVD in the elderly are more limited. According to the results of a meta-analysis of 8 RCTs (n=24674; mean age 73.0±2.9 years; follow-up period 3.5±1.5 years), statins significantly reduce the incidence of MI and stroke in elderly people with a high risk of developing CVD, but do not significantly extend life expectancy in the short term [19]. In another meta-analysis, there were 8 RCTs (25,952 individuals ≥65 years of age) statins significantly reduced the combined endpoint that included major adverse cardiovascular events, non-fatal MI, and MI in general, but the effect of statins on fatal MI, stroke (fatal and non-fatal), and overall mortality was statistically unreliable [7]. The incidence of myalgia, increased levels of hepatic transaminases, new cases of diabetes mellitus, serious HP, and drug withdrawal due to HP did not differ from that in the control group. The authors of the meta-analysis concluded that the benefits of statins may exceed the risks associated with their use, but recommended further research to determine the role of statins in the prevention of fatal MI, stroke, and all-cause mortality. Prior to 2015, the START criteria recommended the use of statins for primary prevention in elderly patients with diabetes mellitus, but this recommendation was removed from the latest version due to insufficient evidence [18]. In most international guidelines, the decision on missile defense is madeprimary prevention measures for the elderly are recommended to be taken on an individual basis, taking into account the cardiovascular risk and weighing the potential benefits and risks.

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Conclusion Thus, the efficacy and safety of lipid-lowering agents as drugs for the primary and secondary prevention of CVD associated with atherosclerosis in patients 80 years and older, representing the fastest growing population group and having the highest risk of CVD development and their adverse outcomes, remains virtually unknown. It is necessary to conduct clinical studies with the participation of this category of the population, including those with "fragility", polymorbidity and polyplasmasia. In addition, it is necessary to develop reliable tools for predicting relevant outcomes in elderly patients (for example, stroke, functionality/independence from the help of others, and quality of life), which will allow evaluating the rationality of lipid-lowering therapy and its effectiveness in this category of patients [23].

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