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THE EFFICACY OF OMEGA-3 UNSATURATED FATTY ACIDS (ICOSAPENT ETHYL) IN REDUCING TRIGLYCERIDES – MECHANISMS AND EVIDENCE

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ЭФФЕКТИВНОСТЬ ОМЕГА-3 НЕНАСЫЩЕННЫХ ЖИРНЫХ КИСЛОТ (ИКОСАПЕНТ ЭТИЛА) В СНИЖЕНИИ УРОВНЯ ТРИГЛИЦЕРИДОВ – МЕХАНИЗМЫ И ДОКАЗАТЕЛЬСТВА

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Abstract. In recent years, cardiovascular diseases have increased sharply. This is because it has been established that not only cholesterol but also triglycerides (TG) play an important role in their development. In particular, patients with hypertriglyceridemia have a higher risk of atherosclerosis and cardiovascular complications. Although statins lower cholesterol levels, a “residual lipid risk” remains in some patients, meaning that even after a patient takes a statin and lowers their cholesterol, the risk of cardiovascular disease is not completely eliminated. This is because it is a different lipid problem, with triglycerides often being at the root of the issue. For this reason, interest has grown in omega-3 polyunsaturated fatty acids, particularly the eicosapentaenoic acid (EPA)-based drug icosapent ethyl.

Аннотация. В последние годы наблюдается резкий рост числа сердечно-сосудистых заболеваний. Это связано с тем, что установлено: важную роль в их развитии играет не только холестерин, но и триглицериды (ТГ). В частности, у пациентов с гипертриглицеридемией повышен риск атеросклероза и сердечно-сосудистых осложнений. Хотя статины снижают уровень холестерина, у некоторых пациентов сохраняется «остаточный липидный риск», то есть даже после приема статинов и снижения уровня холестерина риск сердечно-сосудистых

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заболеваний не устраняется полностью. Это связано с тем, что речь идет о другой липидной проблеме, в основе которой часто лежат триглицериды. По этой причине возрос интерес к полиненасыщенным жирным кислотам омега-3, в частности к препарату икосапент этил на основе эйкозапентаеновой кислоты (ЭПК).

Keywords: cholesterol, omega-3, hypertriglyceridaemia, lipoprotein.

Ключевые слова: холестерин, омега-3, гипертриглицеридемия, липопротеины.

Icosapent ethyl is a highly purified ethyl ester form of eicosapentaenoic acid (EPA), primarily used in the treatment of moderate to severe hypertriglyceridemia. The drug is converted into the active form of EPA in the body, exerting a multi-level effect on lipid metabolism [1, 6].

Clinical studies show that icosapent ethyl not only leads to a reduction in triglyceride levels but also decreases the concentration of VLDL and triglyceride-rich remnant lipoproteins [1].

This effect is mainly attributed to a reduction in triglyceride synthesis and an increase in fatty acid beta-oxidation in the liver [6].

Furthermore, the effect of the drug extends beyond the lipid profile to also influence the pathological processes occurring in the vessel wall. EPA reduces endothelial dysfunction, attenuates the formation of oxidized cholesterol, and lowers chronic inflammatory activity in the vessel wall [3, 6].

Looking specifically at the EVAPORATE study, we see that icosapent ethyl reduces the volume of atherosclerotic plaques in the coronary arteries and helps to stabilise them [3].

The primary aim of the study was to see how the atherosclerotic plaques inside the arteries changed. During the study, the plaques in the patients' coronary arteries were measured using a special imaging technique (CT angiography). They were then all given a statin, and in addition, one group of patients was given icosapent ethyl. When the results were examined, it was observed that in patients receiving icosapent ethyl, the atherosclerotic plaques had reduced and become more stable. Another high-level, global study, REDUCE-IT, confirmed that these effects translate into clinical outcomes by demonstrating a reduction in major cardiovascular events [2].

In this study, the mechanism was investigated in over 8,000 people. The same mechanism and the same drug, but with a different effect, were studied. At the end of this study, it was determined that in those taking icosapent ethyl, the incidence of heart attack, stroke, and death from cardiovascular disease was reduced by ~25%. Overall, meta-analyses and clinical trials from recent years have highlighted that the cardiovascular benefit of EPA-based therapy is associated not only with the reduction of triglycerides but also with anti-inflammatory, antioxidant, and pleiotropic vascular protective mechanisms [2, 4, 6].

To elaborate, it can be concluded that EPA (icosapent ethyl) acts on the cardiovascular system in several different ways, not just by lowering triglycerides. This includes reducing inflammation in the vessel wall and the oxidation of cholesterol, thereby protecting the vessel. Regarding the mechanisms of the triglyceride-lowering effects of icosapent ethyl: one of the main mechanisms of action of icosapent ethyl is to reduce the synthesis of triglycerides in the liver. Specifically, EPA inhibits the conversion of fatty acids into triglycerides in the liver. It also reduces the synthesis of the lipoprotein particle that transports endogenous triglycerides from the liver to peripheral tissues, namely VLDL. As a result, the blood triglyceride level is lowered [6].

Furthermore, EPA increases the beta-oxidation of fatty acids. During this process, fatty acids are broken down for energy production, thereby reducing lipid accumulation in the liver [6].

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Another important mechanism is the increased activity of the enzyme lipoprotein lipase. Lipoprotein lipase is an enzyme located in the walls of blood vessels, whose main function is to break down triglycerides. This enzyme accelerates the breakdown of triglyceride-rich lipoproteins and increases their clearance from the blood [1].

Studies have shown that icosapent ethyl also has anti-inflammatory and antioxidant effects. The drug reduces inflammation, improves vascular endothelial function, and increases the stability of atherosclerotic plaques [3].

Clinical studies and scientific evidence

The efficacy of icosapent ethyl (EPA-based therapy) in reducing triglycerides and cardiovascular risk has been extensively demonstrated by large clinical studies and meta-analyses conducted in recent years. This evidence is not limited to its effects on lipid levels but also demonstrates a direct impact on clinical outcomes (heart attack, stroke, and death).

The primary analyses conducted as part of the programme and its various sub-analyses, including the REDUCE-IT USA sub-analysis, have shown that the cardiovascular benefit of icosapent ethyl is not limited to a particular country, ethnicity, or clinical sub-population, but is consistent and reproducible across broad patient groups. In this study, more than 8,000 patients with elevated triglyceride levels and high cardiovascular risk on statin therapy were enrolled for long-term observation, with patients randomized to receive either icosapent ethyl (4 g/day) or a placebo.

In subgroup analyses, patients from the US, Europe, and other regions were analysed separately, and a similar risk reduction for the primary cardiovascular endpoints (of approximately 20–30%) was observed across all geographical regions. This result demonstrated that the drug's effect was independent of geographical and ethnic variation. Furthermore, similar results were obtained in subanalyses by diabetes status, establishing that the cardiovascular benefit was consistent in patients with and without type 2 diabetes. This is particularly important, as the diabetic population typically has higher residual lipid and inflammatory risk. Furthermore, stratification analyses by baseline triglyceride levels, HDL-cholesterol levels, renal function, and other clinical risk markers have also shown that the cardioprotective effect of icosapent ethyl is consistently maintained across different risk profiles. This supports the fact that the drug's mechanism of action is not limited to triglyceride reduction, but is also associated with pleiotropic mechanisms such as reducing inflammation, improving endothelial function, mitigating oxidative stress, and stabilising atherosclerotic plaque [4].

Thus, the large-scale clinical and subanalytic evaluations conducted within the REDUCE-IT programme have demonstrated that icosapent ethyl has a universal effect in reducing residual cardiovascular risk, and that this effect does not vary significantly across diverse demographic, metabolic, and geographical factors. These findings further reinforce the clinical significance of EPA-based therapy in modern lipidology, forming a key scientific basis that supports its use as an adjunct to standard therapy in high-risk patient groups.

One of the most important sub-analyses conducted as part of the REDUCE-IT programme was a separate assessment of the cardiovascular benefit of ethyl esters of eicosapentaenoic acid in patients with type 2 diabetes. In this subanalysis, patients with elevated triglyceride levels and high cardiovascular risk on statin therapy were separately stratified according to their diabetes status. Patients with type 2 diabetes were analysed as an independent group.

The study's findings showed that although patients with type 2 diabetes had higher baseline cardiovascular risk, greater residual lipid abnormalities, and increased inflammatory activity overall, the use of icosapent ethyl led to a significant reduction in major cardiovascular events (myocardial infarction, stroke, and cardiovascular death) in this population. The maintenance of the risk reduction, consistent with the overall REDUCE-IT results, demonstrated that the drug retains its efficacy even

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in the diabetic metabolic environment. This subanalysis particularly highlighted that the high triglyceride levels, increased atherogenic lipoproteins, and chronic inflammatory state observed in the context of diabetic dyslipidaemia do not attenuate clinical benefit, despite the effects of icosapent ethyl. Conversely, in this high-risk group, the reduction in relative and absolute risk led to more clinically significant outcomes [4].

Thus, The REDUCE-IT DM subanalysis has shown that icosapent ethyl is particularly effective in reducing residual cardiovascular risk in patients with type 2 diabetes, and its benefit is attributed not only to improvements in the lipid profile but also to pleiotropic mechanisms such as reduced inflammation and improved vascular function. These findings strongly support the use of EPA-based therapy as an adjunctive treatment strategy in the setting of diabetic dyslipidaemia. Systematic reviews and meta-analyses from 2021 to 2023 have evaluated the effect of omega-3 fatty acids on cardiovascular outcomes in the context of various formulations and preparations. The primary objective of these analyses was to compare the clinical efficacy of EPA-based monotherapy versus combination EPA+DHA preparations [7].

Meta-analytical findings have shown that high-purity EPA-based therapy (particularly in the form of ethyl-icosapent) demonstrates a more stable and consistent benefit in terms of reducing cardiovascular events. This benefit has been largely attributed to reductions in triglycerides, modification of atherogenic lipoproteins, and attenuation of vascular inflammation. In particular, data from randomised clinical trials have shown that EPA-based therapy is associated with a statistically and clinically significant reduction in major cardiovascular endpoints (myocardial infarction, stroke, and cardiovascular death).

In contrast, the results for combined EPA and DHA preparations have been more heterogeneous, with some studies observing minimal or inconsistent cardiovascular benefit. Potential reasons for this discrepancy have included the differential effect of DHA on lipid fractions, its effect on LDL-cholesterol levels, and the relative attenuation of EPA's anti-inflammatory effect. Consequently, the clinical efficacy of mixed omega-3 formulations has been less predictable [8].

The overall conclusion of these meta-analyses is that high-purity EPA-based therapy has a more consistent and robust evidence base for the reduction of cardiovascular risk. This supports the hypothesis that “pure EPA has a superior cardioprotective effect compared to blends” and provides the scientific basis for the consideration of icosapent ethyl as one of the preferred choices in clinical practice. It is considered one of the earliest and most important sources of long-term evidence demonstrating the cardiovascular effects of EPA-based therapy and was re-evaluated in 2020 with updated analyses. This was a large-scale, open-label, randomised clinical trial conducted in Japan that evaluated the effect of adding EPA to statin therapy on cardiovascular outcomes. In the study, patients were divided into two groups: one group received statin therapy alone, while the other group took daily EPA (eicosapentaenoic acid) alongside the statin. Long-term follow-up results showed that the group receiving EPA supplementation experienced a significant reduction in major cardiovascular events (coronary events, non-fatal myocardial infarction, and other ischaemic events) [11].

Updated analyses have shown that this benefit is particularly pronounced in patients with high triglyceride levels and diabetes. In these subgroups, the effects of EPA on atherogenic lipoproteins, the reduction of vascular inflammation, and the improvement of endothelial function were associated with more pronounced clinical outcomes.

Thus, the updated results of the JELIS study show that EPA-based therapy has demonstrated a cardiovascular protective effect not only in modern studies (e.g., the REDUCE-IT trial) but also in historical clinical evidence. This confirms that EPA is a long-term cardioprotective agent that influences real clinical outcomes, in addition to its lipid-lowering effect, and reinforces its importance in modern therapy.

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This serves as an observational cohort study in clinical practice, assessing the effectiveness of icosapent ethyl and aiming to verify the extent to which the results of randomised clinical trials can be replicated in routine healthcare. In these types of studies, patients are selected from real-world hospital and outpatient practices and are followed up in more “real-world” settings, unlike in rigorous clinical trial protocols.

In cohort analyses conducted in 2022, the rates of hospitalisation, myocardial infarction, and other ischaemic events were assessed in high cardiovascular-risk patients receiving icosapent ethyl. The results showed that the cardiovascular benefit observed in the REDUCE-IT trial is significantly replicated in real-world clinical practice, with a similar trend in risk reduction maintained.

At the same time, the analyses showed that patient adherence directly impacts the outcomes. Thus, real-world evidence shows that the cardioprotective effect of icosapent ethyl, proven in randomised clinical trials, is also replicated in routine clinical practice. Adherence to the medication makes the reduction in cardiovascular events more consistent and predictable. Cohorts with high adherence were observed to have lower rates of myocardial infarction and hospitalisation, indicating that clinical effectiveness is maintained in real-life settings [12].

Thus, real-world evidence shows that the cardioprotective effect of icosapent ethyl, proven in randomised clinical trials, is replicated in daily clinical practice. These findings confirm that its efficacy is not limited to controlled trial settings but is also clinically significant in a real-world patient population. A randomised, placebo-controlled clinical study conducted to investigate the effect of icosapent ethyl on triglyceride levels in patients with severe hypertriglyceridaemia. In this study, patients were given ikosapent ethyl (EPA) as monotherapy, and their lipid profiles were monitored over a period of time. The results of the study showed that icosapent ethyl significantly reduces triglyceride levels in the blood and weakens the synthesis of triglycerides in the liver. At the same time, the amount of triglyceride-carrying lipoproteins called VLDL decreases, and their clearance from the blood is faster. As a result, the overall lipid burden is reduced and the blood lipid profile improves. These findings indicate that ikosapent ethyl has a potent lipid-lowering effect, particularly in severe hypertriglyceridaemia, and simultaneously inhibits the synthesis and transport of fats in the liver [9].

A randomised clinical study conducted to evaluate the additional lipid-lowering effect of ethyl esters of eicosapentaenoic acid (EPA) in patients receiving statin therapy who nevertheless have high triglyceride levels (residual hypertriglyceridaemia). The primary aim of this study was to determine the extent to which EPA could have an effect on the remaining “residual lipid risk”, even though statins reduce LDL cholesterol. The results of the study showed that when added to statin therapy, ikosapent ethyl significantly and additionally reduces triglyceride levels, which is associated with the inhibition of triglyceride synthesis in the liver and a reduction in VLDL production. Furthermore, it improves not only triglycerides but also broader lipid profiles; non-HDL cholesterol is reduced, indicating a lower burden of total atherogenic (vessel-damaging) lipoproteins in the blood. A reduction in apolipoprotein B (ApoB) levels was also observed, which means a reduction in the “number of particles” involved in atherosclerosis. In other words, not only is the amount of cholesterol reduced, but the total number of harmful particles carrying cholesterol is also reduced [10].

These findings indicate that eicosapent ethyl not only affects triglycerides but also comprehensively improves the overall atherogenic lipoprotein profile. Therefore, it is considered an add-on therapy of clinical significance for reducing residual lipid risk despite statin therapy, and contributes to a further reduction in cardiovascular risk.

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Study	*Patient Population*	*Primary Intervention*	*Main Outcome*	*Clinical Significance*
REDUCE-IT Trial	Patients receiving statin therapy with elevated triglyceride levels and high cardiovascular risk	Icosapent ethyl 4 g/day	Approximately 25% reduction in major cardiovascular events	Clinically significant reduction in cardiovascular risk
REDUCE-IT Subanalysis	Patients with type 2 diabetes mellitus	Icosapent ethyl versus placebo	Sustained reduction in MACE among diabetic patients	Efficacy maintained in diabetic dyslipidemia
Omega-3 Meta-analysis	Various randomized controlled trials (RCTs)	EPA and EPA+DHA formulations	EPA demonstrated more consistent cardiovascular benefit	Superiority of purified EPA established
JELIS Updated Analysis	Patients receiving statin therapy plus EPA	EPA add-on therapy	Reduction in coronary events	Evidence supporting cardiovascular protection
Cohort Study	Patients in real-world clinical practice	Use of icosapent ethyl	Reduction in hospitalization and myocardial infarction (MI)	Confirmation of clinical trial findings in routine practice
MARINE Trial	Patients with severe hypertriglyceridemia	EPA monotherapy	Significant reduction in triglyceride levels	Potent triglyceride-lowering effect
ANCHOR Trial	Patients with residual hypertriglyceridemia despite statin therapy	Icosapent ethyl add-on therapy	Reduction in triglycerides, non-HDL-C, and ApoB	Reduction of residual lipid-related cardiovascular risk

Icosapent Ethyl is generally considered a well-tolerated agent with a favorable safety profile, and clinical studies have demonstrated that serious adverse events associated with its use are uncommon. The most frequently reported side effects are typically mild and transient, predominantly involving the gastrointestinal system. These include dyspepsia, abdominal discomfort, and mild digestive disturbances. Arthralgia has also been reported in some patients; however, these symptoms rarely necessitate discontinuation of therapy.

Large-scale clinical investigations, particularly analyses conducted within the REDUCE-IT Trial program, have identified a slight increase in certain specific risks associated with icosapent ethyl therapy. One such finding was a modest elevation in the incidence of atrial fibrillation. This increase was observed mainly among elderly individuals and patients at high cardiovascular risk. Although clinically relevant and requiring monitoring, this observation did not alter the overall favorable benefit–risk profile of the therapy. Another potential concern is a slight increase in bleeding tendency. This effect warrants particular attention in patients receiving concomitant anticoagulant or antiplatelet therapy. Nevertheless, extensive analyses have demonstrated that serious or life-threatening bleeding events remain rare, with the overall incidence remaining low.

Overall, current clinical evidence indicates that the cardiovascular benefits of icosapent ethyl—especially the reduction in the risks of myocardial infarction, stroke, and cardiovascular mortality—outweigh its potential risks. Consequently, the agent is regarded as a safe and effective adjunctive therapy in patients at high cardiovascular risk and is recommended in international clinical guidelines.

Conclusion

Contemporary clinical and experimental evidence demonstrates that icosapent ethyl is a multifaceted and clinically significant therapeutic agent in the management of hypertriglyceridemia and the reduction of residual cardiovascular risk despite ongoing statin therapy. Its principal lipid-lowering effects are mediated through the suppression of hepatic triglyceride synthesis, reduction of

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very-low-density lipoprotein (VLDL) production, and enhancement of lipoprotein lipase activity, mechanisms that collectively lead to a substantial decrease in circulating triglyceride levels. Importantly, the clinical benefits of icosapent ethyl extend beyond lipid modification alone. Eicosapentaenoic acid exhibits potent anti-inflammatory and antioxidant properties, thereby reducing chronic vascular inflammation, improving endothelial function, and slowing the progression of atherosclerotic plaque formation. These pleiotropic effects further strengthen its cardioprotective profile and distinguish it from conventional lipid-lowering therapies. The clinical relevance of these mechanisms has been confirmed by large randomized clinical trials. The REDUCE-IT trial demonstrated a significant reduction in major cardiovascular events, including myocardial infarction, stroke, and cardiovascular mortality, whereas the EVAPORATE trial provided evidence of decreased atherosclerotic plaque volume and enhanced plaque stabilization within coronary arteries. Furthermore, studies such as the MARINE trial and ANCHOR trial confirmed its beneficial effects on lipid parameters and its role in reducing residual lipid-associated cardiovascular risk. In addition, real-world evidence and multiple subgroup analyses have shown that these benefits are reproducible not only under controlled clinical trial conditions but also in routine clinical practice. Consistent outcomes observed particularly among patients with diabetes mellitus and other high-risk populations further support its broad therapeutic applicability. In conclusion, icosapent ethyl is currently regarded in modern lipidology not merely as a triglyceride-lowering agent, but also as a pleiotropic therapeutic strategy capable of modulating multiple mechanisms involved in the pathogenesis of atherosclerosis and improving cardiovascular outcomes. Owing to these properties, it represents an evidence-based and clinically important contemporary treatment option for reducing residual cardiovascular risk in high-risk patient populations.

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