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Original Research Article

Effectiveness of omega-3 fatty acids in the management of hypertriglyceridemia: a multi-centre retrospective study

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ABSTRACT

Background: Hypertriglyceridemia is increasingly prevalent in India and represents a major contributor to atherosclerotic cardiovascular disease and overall cardiometabolic risk. Although large global trials have demonstrated the triglyceride-lowering efficacy of Omega-3 fatty acids (O3FA), real-world evidence regarding their effectiveness, safety, and prescribing patterns in the Indian population remains scarce. This study aimed to evaluate the real-world effectiveness, safety, and utilization patterns of O3FA therapy in Indian patients with hypertriglyceridemia.
Methods: This retrospective, multicentre observational study analyzed medical records of patients diagnosed with hypertriglyceridemia who were prescribed O3FA between January 2023 and April 2024 across multiple healthcare centers in India. Demographic details, treatment duration, lipid parameters, glycemic indices, and adverse events were assessed.
Results: A total of 447 patient records were included in the analysis. The majority were male (80.3%), with a mean age of 49.5 years. Patients received one O3FA capsule daily for a mean duration of 2.09 months. Statistically significant and clinically meaningful improvements were observed in lipid parameters: triglycerides decreased by 113.42 mg/dl, total cholesterol by 75.99 mg/dl, LDL-C by 49.15 mg/dl, and VLDL by 13.99 mg/dl, while HDL-C increased by 16.47 mg/dl ($p<0.001$ for all). Glycemic control also improved, with reductions in fasting blood glucose (−24.79 mg/dl), postprandial glucose (−10.17 mg/dl), and HbA1c (−0.94%). Only four patients reported mild gastrointestinal adverse events, and no serious adverse events were documented.
Conclusions: O3FA therapy demonstrated significant improvements in lipid and glycemic parameters with an excellent safety profile, reinforcing its role as an effective and well-tolerated cardiometabolic intervention in routine Indian clinical practice.

Keywords: Cardiovascular, Cholesterol, Docosahexaenoic acid, Eicosapentaenoic acid, Triglycerides

INTRODUCTION

Hypertriglyceridemia is emerging as a major health concern for Indians, contributing significantly to the rising burden of atherosclerotic cardiovascular disease (ASCVD).[1] India is undergoing a rapid transition, driven by urbanization, dietary shifts, sedentary lifestyles, and population ageing, which has led to a sharp rise in lipid and glycaemic abnormalities across both urban and rural areas.[1] Following the ICMR-INDIAB study (2023), the national prevalence of hypertriglyceridemia (≥150 mg/dl) is 32.1%, with low HDL-C impacting 66.9% of the population, and hypercholesterolemia is estimated to be seen in 24.0% of Indian adults.[2]

These demographics highlight the widespread nature of lipid abnormalities, with implications for cardiometabolic morbidity and mortality. Lipid disorders disproportionately affect males, as mentioned in the India Heart Watch and Jaipur Heart Watch Series, reporting males having elevated triglycerides and LDL-C compared

with females.[3] Alarmingly, lipid abnormalities are no longer an issue with older adults. A study from the Comprehensive National Nutrition Survey (2016-2018) has revealed that 77% of young Indians had at least one lipid disorder, with low HDL-C and elevated triglycerides being the most prevalent reasons.[4]

The therapeutic management of elevated triglycerides, specifically for those with very high levels (≥ 500 mg/dl), must be clinically prioritised to prevent them from acute complications such as pancreatitis.[5] In such scenarios, the primary goal is to lower triglyceride levels and to keep them below 500 mg/dl. However, in individuals with mild to moderate hypertriglyceridemia, the focus has to be on mitigating long-term cardiovascular risk.

For that there are certain clinical guidelines to be followed in addressing secondary causes. Such steps are important before considering pharmacological interventions. These include weight reduction, increased physical activity, reduced alcohol abuse, and good dietary transition, such as limiting refined carbohydrates, trans fats, and increasing intake of unsaturated fats along with omega-3 fatty acid-rich seafood.[6]

Omega-3 fatty acids (O3FA), in particular eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), have been known for their triglyceride-lowering pharmacological properties.[7] It lower plasma triglycerides by suppressing VLDL synthesis, enhancing β-oxidation of fatty acids, and reducing substrate availability for triglyceride formation. Additionally, it modulates inflammatory signaling by competing with arachidonic acid for cyclooxygenase and lipoxygenase enzymes, thereby reducing pro-inflammatory eicosanoid production and attenuating NF-kB cytokine release.[8]

The 2002 American Heart Association (AHA) scientific report mentioned the guidelines for daily dietary intake of 2-4g/day of EPA+DHA for patients with hypertriglyceridemia, under proper physician supervision. A novel AHA science advisory validated the role of O3FA supplementation in lowering ASCVD risk, mainly in patients with elevated triglycerides.[9]

The degree of triglyceride lowering with full-dose prescription O-3 FA (4 g/day providing >3 g/d EPA+DHA) appears to be similar to that of fibrates, although evidence-based studies directly comparing these 2 drug classes in patients with very high triglycerides remain limited.[9,10] Globally, there have been numerous studies regarding the utilisation of O3FA, but in India, it's still comparatively limited.

There is an increasing need for real-world evidence (RWE) to evaluate the efficacy and safety of O3FA in Indian populations with varied demographics and comorbidities. In light of the literature mentioned above, this present study aims to assess the multi-centre retrospective observational study analyzing the utilization patterns, therapeutic effectiveness and safety profile of O3FA in the management of hypertriglyceridemia in clinical practice.

METHODS

Study design

This study was a retrospective study conducted at multiple geographical locations all over India, involving patients with hypertriglyceridemia who had been treated with omega-3 fatty acid capsules between January 2023 to April 2024.

Ethical considerations

This study adhered with the principles outlined in the Declaration of Helsinki and received approval from the independent ethics committee (IEC). The informed consent forms were not required due to the retrospective nature of the study. The study involves the use of anonymised data from the medical records of patients already treated with omega-3 fatty acids therapy.

Data collection

A total of 3044 patient records were scrutinized, out of which 447 patients had complete medical records, which were further taken for analysis. Demographic characteristics, clinical diagnosis, laboratory measurements, vitals, medication use, and adverse events were extracted from each patient's medical record. The data collection was done at the start of therapy (baseline) and at the follow-up visit (3 to 6 months).

Patient selection

Patients aged ≥18 years diagnosed with hypertriglyceridemia, having been prescribed omega-3 fatty acids within the past 12 months, were included. The availability of pretreatment and posttreatment lipid profiles was also a major factor in influencing the inclusion criteria for the study. The patients with insufficient medical record data were excluded from the analysis.

Endpoints

The primary endpoint of the study was to evaluate the change in lipid and glycemic profile levels. Additionally, the study aimed to assess the adverse events reported during the treatment period.

The secondary endpoint was to assess the drug utilization of omega-3 fatty acids among patients with hypertriglyceridemia.

Statistical analysis

Descriptive and summary statistics were calculated to provide an overall perspective of the study data. Continuous data, such as lipid and glycemic parameters,

were summarized using the number of observations (N), mean, and standard deviation (SD) or interquartile range (IQR) wherever applicable. Comparisons of continuous clinical variables between baseline and follow-up visits (3-6 months) were performed using paired t-tests for normally distributed data.

For parameters where the normality assumptions were not met, Wilcoxon signed-rank tests were employed as non-parametric tests. Categorical data, such as incidence of adverse events and drug utilization patterns, were summarized using frequencies and percentages. Statistical analyses were considered significant at a $p<0.05$ significance level. Data were analyzed using SPSS software version 25.0 (IBM Corp., Armonk, NY, USA) and Microsoft Excel.[11,12]

RESULTS

Baseline characteristics of the patient

A medical record of a total of 447 patients was included in the analysis. The proportion of male patients (80.3%) was significantly higher than female patients (19.7%). The mean age of enrolled patients was 49.50 years (SD=±10.32), with an age range of 28 to 94 years. The average height and weight of patients were 165.64 cm (SD=±6.26), observed between the range of 149 to 190, and 71.27 kg (SD=±10.60), ranging between 45 to 157 kg (Table 1).

Analysis of vital parameters

A significant increase in respiratory rate and a significant decrease in body temperature was observed in patients from baseline to the follow-up stage. However, these changes were minor and not clinically significant. Pulse rate and oxygen saturation had shown no significant changes over time. These observations highlight the specific physiological changes documented over the study duration (Table 2).

Medical history and conditions of the patient

The included patients had reported their medical history and conditions, which accounted for diseases such as hypertension and diabetes mellitus. Hypertension was more prevalent, affecting 143 subjects, representing 31.99% of the data analyzed. Diabetes mellitus was reported in 56 individuals, accounting for 12.53% of the total patient data analyzed (Table 3).

Concomitant medications

Among patients for whom concomitant medication records were available, the most commonly used agents were statins (primarily atorvastatin), taken by 132 patients (29.53%), and antihypertensives (mainly amlodipine), used by 92 patients (20.58%). Antidiabetic therapy with metformin was recorded in 56 patients (12.53%), while antilipemic therapy with fenofibrate was noted in 8 patients (1.79%). Overall, 172 patients (38.48%) were receiving one or more concomitant medications, whereas no concomitant medication records were available for 275 patients (Table 4).

Drug utilisation of omega-3 fatty acids by the patient

All included patients (447, 100%) were prescribed a dosage of one omega-3 fatty acid capsule a day. The dose of O3FA (DHA & EPA) is varied widely in patients from 90 mg to 2000 mg. The therapeutic dosage averaged for 2.09 months, with a deviation of 1.002 months, for a period of 1 to 6 months. This indicates a consistent daily dosing schedule within the included individuals with variable treatment lengths (Table 5).

Drug's effect on lipid and glycemic parameters

Significant improvements were observed in all the measured parameters ($p<0.05$), except serum creatinine, which showed a -0.01 change, from 0.87 to 0.88, resulting in no significant effect. Triglyceride levels decreased by 113.42 mg/dl on average, from 289.14 to 175.72. Total cholesterol reduced by 75.99 mg/dl, ranging from 239.32 to 163.32 mg/dl. LDL levels dropped by 49.15 mg/dl, from 158.77 to 109.62, whereas HDL levels increased by 16.47 mg/dl, from 45.23 to 61.70. VLDL levels were also decreased by 13.99 mg/dl, ranging from 37.42 to 23.43, among 422 patients (Figure 1).

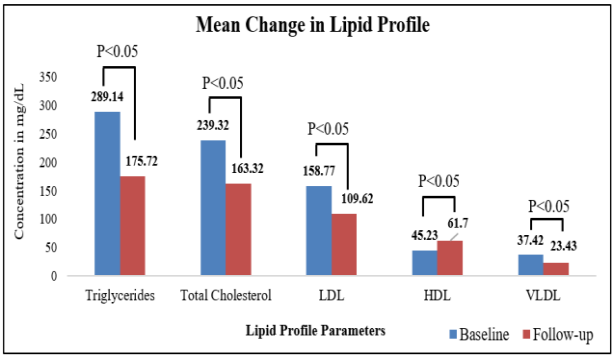

Figure 1: Effect on lipid parameters.

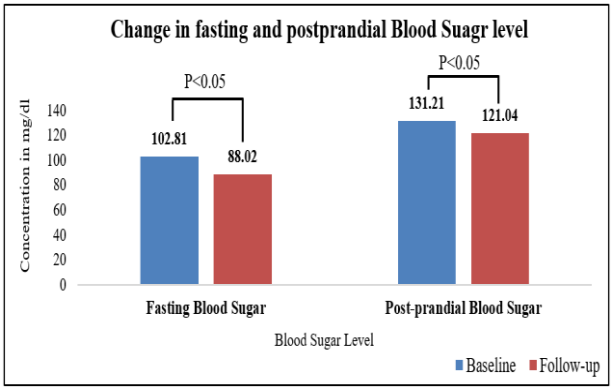

Figure 2: Effect on glycaemic parameters.

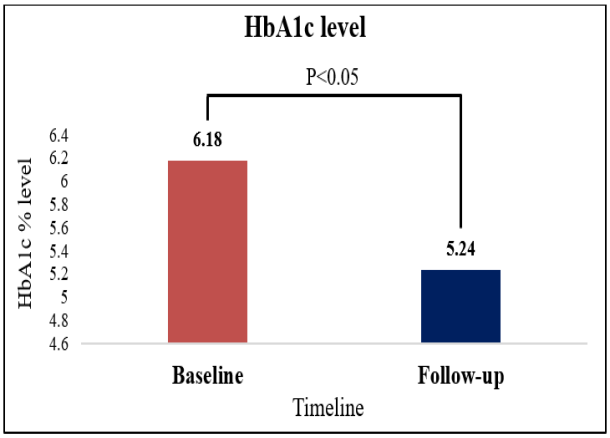

Figure 3: Effect on HbA1c level (Mean change from baseline to follow-up).

Fasting blood sugar was reduced by 24.79 mg/dl, from 102.81 to 78.02, in 155 patients. Postprandial blood sugar had a change of 10.17 mg/dl, from 131.21 to 121.04. HBA1C was found to have reduced by 0.94 mg/dL, from 6.18 to 5.24. All these changes were statistically sound and significant, indicating effective lipid and glycaemic profile improvement over the study duration (Figures 2 and 3).

Drug's safety analysis on adverse events

Safety analysis showed that only four patients suffered from mild gastrointestinal disturbances. These events were transient, self-limiting and did not necessitate the discontinuation of therapy. Importantly, no severe or life-threatening adverse events were reported throughout the study duration, emphasizing the favourable tolerability profile of the treatment.

Table 1: Demographic characteristics.

Characteristics		Mean±SD, IQR, n (%)
Gender	Male	359, (80.3%)
	Female	88, (19.7%)
Age (in years)		49.50±10.32, (28-94), 447
Weight (in kg)		71.27±10.60, (45-157), 270
Height (in cm)		165.64±6.26, (149-190), 348
BMI (in kg/m^2)		27.83±3.61, (17.15-40.35), 171

Table 2: Vital parameters.

Vital signs (units)	N	Baseline (Mean±SD)	Follow-up (Mean±SD)	Change (Mean±SD)
Pulse (BPM)	165	76.76±11.51	75.52±8.99	1.24±13.20
Respiration rate (breaths/min)	153	14.76±2.02	16.29±4.23	-1.53±4.46
Temperature (°F)	155	98.02±0.73	97.58±0.60	0.43±0.81
SPO$_2$ (%)	151	96.56±2.01	96.29±2.88	0.27±3.10

Table 3: Medical history and conditions.

Condition	Frequency (%)
Hypertension	143 (31.99)
Diabetes mellitus	56 (12.53)

Table 4: Concomitant medications.

Medication class	Frequency (%)
Statins (Atorvastatin)	132 (9.53)
Antihypertensives (Amlodipine)	92 (20.58)
Antidiabetics (Metformin)	56 (12.53)
Antilipemic (Fenofibrate)	8 (1.79)
Total patients on one or more concomitant medications	172 (38.48)
Total patients with no available data about concomitant medications	275 (61.52)

Table 5: Drug utilisation of omega-3 fatty acids.

Parameter	Value
Frequency of administration, N (%), 1 capsule per day	447 (100%)
Duration of therapy (in months), Mean±SD, Range	2.09±1.002, (1-6)

DISCUSSION

This multi-centre, real-world evidence-based, retrospective study provides thorough evidence on the utilisation, efficacy, and safety of O3FA in the management of hypertriglyceridemia in Indian patients. While O3FA has been extensively evaluated in controlled trials, its application in a diverse Indian population remains underreported. The observations reported in this study serve as a reference point for upcoming studies and clinical trials, supporting healthcare professionals (HCPs). This study would help aid HCPs in assessing and improving patient outcomes.

Furthermore, this study was fundamental in identifying parameters that could be associated with better clinical outcomes and offering real-world insights into how O3FA can be optimised for future therapeutic strategies. Gender disparity was observed in this study, with male patients comprising 80.3% of the total patient data analyzed. This associates well with the national epidemiological survey, indicating a higher male prevalence of lipid abnormalities.[13]

Despite males comprising the majority of the study population, O3FA exhibited a similar magnitude of improvement in key lipid markers and glycaemic parameters in all patients, suggesting that its efficacy is not influenced by gender distribution within the dataset. As known differences in the lipid metabolism associated with cardiovascular disorders exist between different sexes, gender balanced research is essential.

Pharmacologically, O3FA exerts its therapeutic activity of lowering triglyceride levels through multiple pathways. Conventionally, these include effects such as suppression of hepatic lipogenesis, reduced very-low-density lipoprotein (VLDL) production, and enhanced fatty acid oxidation.[8] Nevertheless, recent findings from Borgfeldt et al have expanded our understanding of O3FA, as they reported that the supplementation in humans leads to the accumulation of N-acyl Taurine's (NATs), specifically C22:6 Nat – a derivative of docosahexaenoic acid (DHA)- in plasma.

This accumulated metabolite disrupts the intestinal triglyceride hydrolysis and absorption, eventually reducing plasma triglyceride levels. Furthermore, C22:6 Nat was also found to increase plasma glucagon-like protein (GLP-1) levels post high-fat meal, suggesting a synergistic effect relevant to glycemic control.[14] This study supports the mechanistic behaviour of O3FA as a dual lipid and glycemic-lowering agent, which aids in observations found in this retrospective study. This reinforces the therapeutic potential of O3FA in individuals with mixed lipid and metabolic abnormalities.

Clinical trial studies further supported the efficacy of O3FA. The REDUCE-IT (NCT01492361) trial evaluated the high dose of eicosapent ethyl, which is a purified form of eicosapentaenoic acid (EPA), a form of O3FA. It is derived from fish oil and is often used to maintain heart health. In the REDUCE-IT trial, EPA significantly reduced triglycerides and major cardiovascular events in patients treated with statins who had elevated triglycerides.[15] Furthermore, the ANCHOR (NCT01047501) trial evaluated O3FA and showed similar triglyceride reductions without elevating LDL-C levels, whereas the JELIS (NCT00231738) trial conducted in Japan had EPA supplementation reporting reduced coronary events.[16,17]

These trial findings align well with the findings, and they support the integration of O3FA into lipid care management in high-risk populations. In this study, the statistically significant reductions were observed in triglycerides, total cholesterol, LDL-C, and VLDL, alongside an increase I HDL-C, suggesting the O3FA therapy has shown a significant lipid-improving effect. Improvements in the glycemic parameters such as fasting blood glucose, HBA1C, and postprandial glucose further support the metabolic benefit of O3FA, specifically in patients with co-existing diseases such as diabetes and hypertension. For the vital parameters, though they showed statistically significant outcomes, they were clinically insignificant.

The study reported only mild gastrointestinal disturbances, with no severe adverse events, thereby strengthening the safety profile of O3FA. The findings of the study remain consistent with the prior evidence about O3FA of reducing systemic inflammation and enhancing insulin sensitivity.[18] The clinical utility of O3FA is reinforced in this study by improving lipid and glycemic parameters among Indian patients suffering from hypertriglyceridemia.

The inclusion of mechanistic insights, in context to its efficacy and global clinical trial evidence, provides a comprehensive understanding of O3FA's therapy. Such studies are essential in refining the personalised treatment strategies for dyslipidaemia management and lowering the cardiovascular risk.

Limitations

The retrospective study design introduces inherent limitations, such as potential bias in data collection and the control over confounding variables. Also, the dose of O3FA (EPA and DHA) is widely varied. Furthermore, the absence of a control or comparator restricts the ability to conduct inferences regarding the efficacy of O3FA therapy. Additionally, the short mean duration of therapy (2.09 months) and limited follow-up period (3 to 6 months) further limit the efficacy of O3FA in long-term evaluation of lipid and glycemic parameters. Despite these limitations, the study provides exceptional insights into the efficacy of O3FA across varied socio-demographic variables and clinical parameters in Indian patients with hypertriglyceridemia.

Future scope

Future research should employ prospective study designs with longer follow-up visits. The study should also incorporate neutral arms as a comparator (placebo or standard therapy) to provide more significant evidence. Such study designs allow for better control of confounding factors and strengthen the assessment for long-term efficacy of O3FA. Addressing these gaps will be essential in optimising the clinical application of O3FA in the therapeutic management of hypertriglyceridemia.

CONCLUSION

This study contributes to the valuable real-world evidence on the efficacy and safety of O3FA in the management of hypertriglyceridemia within the Indian landscape. It demonstrated statistically significant improvements in the lipid and glycemic levels, with specific reductions in triglycerides, LDL-C, and total cholesterol, and a favourable rise in HDL-C. Overall, the study emphasises the importance of integrating O3FA into preventive care strategies for lipid abnormalities, particularly in countries like India, where the burden of hypertriglyceridemia is rapidly increasing. Future clinical/prospective studies should have longer follow-up time points and optimized dosing of O3FA to maximize the patient outcomes.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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