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THE SAFETY AND EFFICACY OF A NOVEL ANTI-HYPERLIPIDEMIC MEDICATION, SEBELIPASE ALFA: A SYSTEMATIC REVIEW AND META-ANALYSIS

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ABSTRACT

Lysosomal acid lipase deficiency (LALD), a rare disorder of lipid metabolism, is treated with sebelipase alfa, a novel anti-hyperlipidemia drug that is a recombinant human lysosomal acid lipase enzyme. This thorough review and meta-analysis evaluate the safety and efficacy of sebelipase alfa in the treatment of LALD.

Methodology: A comprehensive search was conducted in PubMed, Cochrane, and other databases using keywords including safety, effectiveness, LALD, and sebelipase alfa. These included research published from 2013 to 2024. We considered both planned and retrospective clinical studies of sebelipase alfa versus standard of care (SOC) or placebo. The statistical analysis was conducted using RevMan 5.4.1, and the quality was evaluated using the Newcastle-Ottawa scale.

Result: A total of 12 studies involving 755 individuals met the inclusion criteria. Lipid markers such as LDL-C (-39.46; 95% Cl: -43.57 to -35.35), total cholesterol (-23.75; 95% Cl: -28.38 to -19.11), triglycerides (-21.80; 95% Cl: -27.30 to -16.30), and ApoB (-20.96; 95% Cl: -25.32 to -16.61) are all significantly impacted by sebelipase alfa. There were also noticeable drops in ALT and AST values. HDL values marginally rise. On the other hand, weight increase (OR: 66.36; 95% Cl: 1.80 to 2444.55) and gastrointestinal side effects (OR: 19.38; 95% Cl: 5.49 to 68.33) were more common in individuals using Sebelipase alfa.

Conclusion: Sebelipase alfa's efficacy is supported by the significant improvements in lipid profiles and liver enzyme levels observed in LALD patients. Furthermore, cautious monitoring is necessary for potential side effects such as weight gain and gastrointestinal problems. To avoid adverse effects and improve dosage, more research is required.

KEYWORDS: Sebilipase alfa, Antihyperlipidemic drug, meta-analysis study, systematic review.

INTRODUCTION

Elevated blood lipid levels are another term for hyperlipidemia. Lipoproteins transport circulating lipids to various organs for steroid production, hormone synthesis, lipid deposition, and energy utilization. The components of lipoproteins include protein, phospholipids, triglycerides, and esterified and unesterified cholesterol. People in the general population with hyperlipidemia don't show any symptoms [1]. This is a disorder that raises the risk of atherosclerotic disease (ASHD) and coronary heart disease (CHD) in blood vessels. A sedentary lifestyle, obesity, smoking, and other risk factors can cause hyperlipidemia [2]. Apolipoproteins, which come in many forms, are proteins that attach to lipids and lipoproteins and transfer them into blood. Chylomicrons are dietary fat carriers that are high in triglycerides (TG). Those are rich carriers of hepatically produced TGs, known as very low-density lipoproteins (VLDL). IDL and LDL are intermediate-density and low-density lipoproteins; these are cholesterol-rich residual particles produced when triglycerides in VLDL are lipolyzed. High-Density Lipoprotein (HDL): A particle high in cholesterol that carries cholesterol to the liver for recycling or elimination. The mean total cholesterol levels in India are rising.

According to recent studies, 25–30% of urban and 15–20% of rural people have elevated cholesterol [3]. Among the risk factors are the two principal forms of hyperlipidemia: inherited primary hyperlipidemia and acquired secondary hyperlipidemia. A patient may be born with a genetic condition that causes primary hyperlipidemia. On the other hand, an underlying reason, such as bad lifestyle choices, drugs (glucocorticoids, amiodarone), hypothyroidism, uncontrolled diabetes, or an unhealthy diet, is what causes secondary hyperlipidemia [4]. Diabetes mellitus, renal failure, nephrotic syndrome, hypothyroidism, and a sedentary lifestyle are a few factors that contribute to hypercholesterolemia and/or high triglycerides [5]. The usage of specific medications, such as beta-blockers, thiazide diuretics, estrogenic-progestin contraceptives, and antiretrovirals, may also be a contributing factor. Blood cholesterol levels can be raised by consuming foods high in saturated fat, cholesterol, and transfat. Smoking, being overweight, not exercising, using steroids, drinking

alcohol, and eating foods rich in cholesterol and saturated fat, such as meat, cheese, processed and fried foods, and egg yolks, can all be avoided to avoid hyperlipidemia [6]. The pathophysiology of primary hyperlipidemia includes idiopathic hyperchylomicronemia, where a malfunction in lipid metabolism results in hypertriglyceridemia and hyperchylomicronemia. This condition is caused by either a lack of the surface apoprotein CI or a malfunction of lipoprotein lipase activity [7].

According to the National Cholesterol Education Program, all persons aged 20 and older should have their fasting lipoprotein profile (FLP), which includes triglycerides, total cholesterol, LDL, and HDL, assessed at least once every 5 years. After a 12-hour or longer fast, it is essential to evaluate HDL, triglycerides, and plasma cholesterol (which are approximately 3% lower than serum readings) because total cholesterol is only slightly affected by fasting, whereas triglycerides may be elevated in non-fasted individuals [8]. The main medication used to treat hyperlipidemia is called a statin. In general, the medications used to treat hyperlipidemia fall into the following categories: Statins, which are inhibitors of HMG-CoA reductase; simvastatin, pravastatin, atorvastatin, rosuvastatin, lovastatin; and bile acid sequestrants (resins)—colestipol, cholestyramine, benzafibrate, gemfibrozil, clofibrate, and fenofibrate—are derivatives of fibric acid. Prevent triglyceride production and lipolysis: Nicotinic acid; others include Gugulipid and Ezetimibe [9]. Along with pharmacological treatment, non-pharmacological measures included reducing daily saturated fat intake to up to 7 percent of daily calories, lowering daily dietary cholesterol intake to less than 200 mg, and reducing total fat intake to 25–35 percent of daily calories. Between 20 and 30 g of soluble fiber can be consumed per day, which is present in several fruits, beans, peas, and oatmeal; and increased consumption of plant sterols or stanols, which are compounds included in nuts and lifestyle modifications, including regular exercise [10]. Evolocumab, alirocumab, bempedoic acid, sebelipase, lomitapide, and evinacumab are among the innovative medications chosen for the treatment of hyperlipidemia. Sebelipase Alfa: A recombinant form of the biological LAL enzyme, sebelipase alfa is used as a long-term alternative treatment for LAL deficiency. N-linked glycans containing mannose and mannose-6-phosphate moieties and terminal N-acetylglucosamine structures are found in Sebelipase alfa. By altering the LAL enzyme, Sebelipase alfa triggers the lysosomal conversion of cholesterol and triglyceride esters into glycerol, cholesterol, and free fatty acids [11]. Sebelipase alfa treatment reduced a number of hepatic and lipid problems associated with lysosomal acid lipase deficiency in both adults and children. (Synageva BioPharma and others provided funding; the ARISE Clinical Trials.gov ID is NCT01757184.) [12]. The FDA has approved Kanuma [sabilipase alfa], a life-changing therapy for those with LAL-D, a terrible, extremely uncommon illness that kills children too soon and damages several organs in those who live [13].

METHODS AND METHODOLOGY

The objective is to assess the safety and effectiveness of the novel anti-hyperlipidemic drug Sebelipase alfa through a meta-analysis. From various prospective and retrospective research studies

Primary Objective: To carry out the literature search and to identify the original work carried out by various researchers related to the novel anti-hyperlipidemic drug Sebelipase alfa.

Secondary Objective: To analyze the data given in the primary objective using the RevMan 5 software.

Several databases were used to conduct a thorough literature search, such as Google Scholar, Embase, PubMed/Medline, Science Direct, the Cochrane Library, and clinical trial registries like (https://clinicaltrials.gov/) in order to track down the clinical reports (of both prospective & retrospective studies). The keywords used for the search and collection of articles are Hyperlipidemia OR Homozygous Familial Hypercholesterolemia for Sebelipase alfa. The keywords used for search And collection of articles are Sebelipase alfa OR Hyperlipidemia OR Lysosomal acid lipase deficiency (LALD) OR Safety & effectiveness of Sebelipase alfa OR safety and effectiveness of sebelipase alfa in infant 'The following trial registries were searched for grey (unpublished) literature: the WHO International Clinical Trials Registry Platform (ICTRP; https://apps.who.int/trialsearch/) and Up-to-date, Elsevier, and International Journal of Lipid Research & Advances. Additionally, preprint sites such as Research Square are considered when searching for grey literature. In addition, we have approached domain experts for help in collecting additional articles on the topic. Our search parameters were not limited to any particular publication language, publisher, or researcher. To locate further publications for research, the reference lists of all pertinent articles are also manually searched.

Inclusion criteria:

- Prospective and Retrospective Studies
- Case Reports
- Clinical Trials carried out on Sebelipase alfa
- Research articles from 01 January 2013 to 30 July 2024 for Sebelipase alfa

We selected papers that matched Sebelipase alfa with a control group that were published between January 1, 2013, and July 30, 2024, as inclusion studies. These studies included in this work involved participants who were diagnosed with lysosomal acid lipase deficiency (LALD) using other lipid-lowering drugs or lipoprotein apheresis or placebo. They were considered as control groups and took sebelipase alfa as a monotherapy or sebelipase alpha with/without lipid-lowering medications. Were considered as a treatment group (intervention). We have done a comparison between Sebelipase alfa (intervention) versus control (comparison) for the safety & efficacy parameters of interest, the evaluation such as efficacy parameters: LDL-C, total cholesterol, HDL, Apo Lipoprotein-B (Apo-B), total triglycerides, ALT, and AST, and safety parameters: Weight gain, gastrointestinal (GI)-related Adverse effects of Sebelipase alfa were evaluated during the course of the study.

Exclusion criteria:
1. Studies which are not related to Topic.
2. Studies that have reported incomplete data.
3. Duplicate Articles
4. Studies that have a language barrier (language not understandable).
5. Research presenting qualitative findings devoid of quantitative information.
6. Preclinical research and in vitro research (animal studies)

The authors of chosen articles were contacted through e-mail for clarification of aroused problems regarding the requirement of complete data of the study. For conducting statistical work in meta-analysis, such studies that were not responded to by authors and are having incomplete data for conducting a statistical review are excluded from the study.

Quality assessment for included studies:
A quality assessment of each of the listed studies has been carried out using the Newcastle-Ottawa scale, and the studies were selected based on the scores obtained.

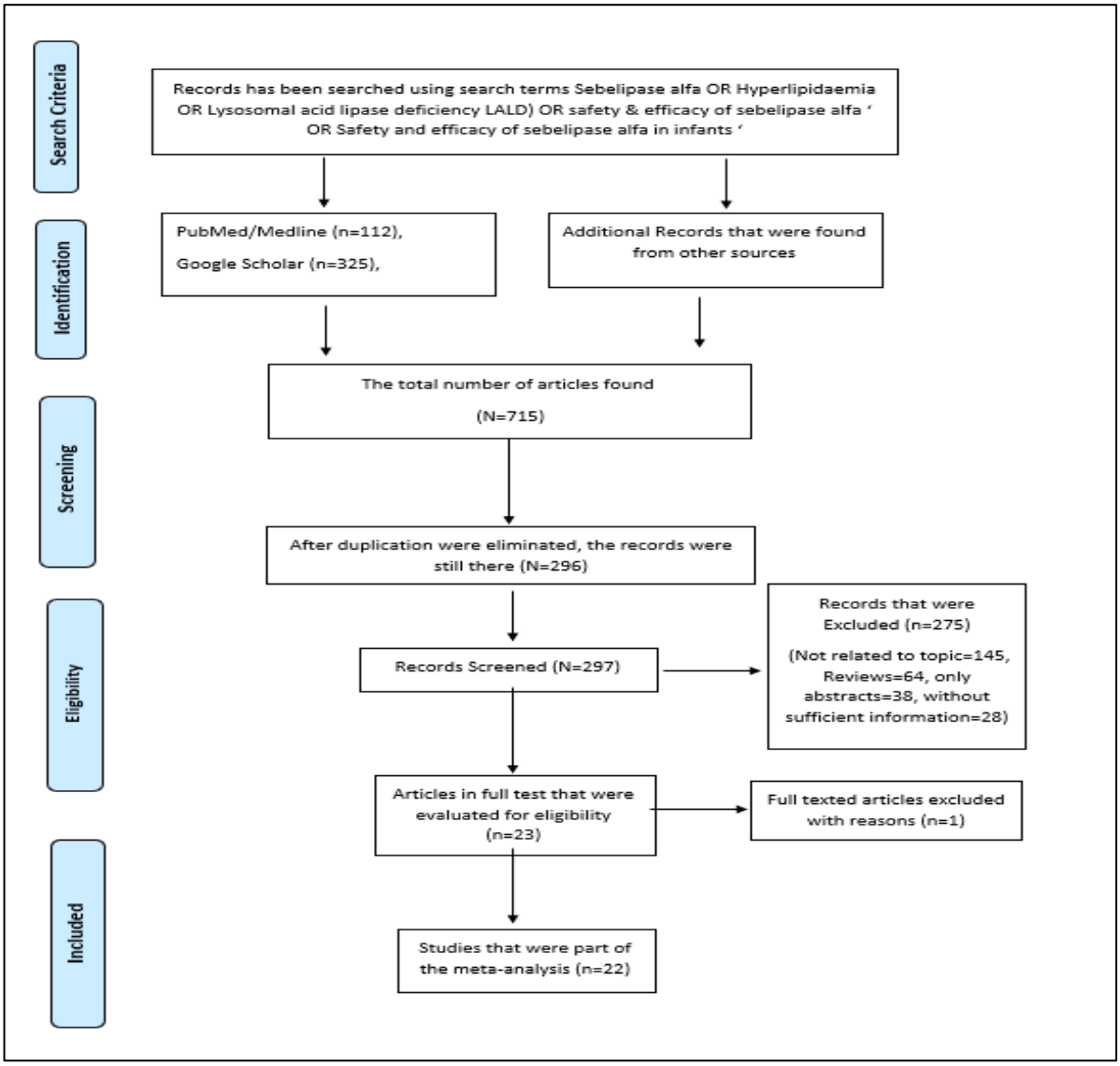
Parameters selected for study: The following parameters related to the safety & efficacy of Sebelipase alfa were analyzed in the study.

- Efficacy Parameters: HDL, Apolipoprotein-B (Apo-B), LDL-C, Total Triglycerides, and Total Cholesterol reduction in elevated ALT, AST levels.
- Safety Parameters: Weight gain, gastrointestinal (GI)-related adverse effects of Sebelipase Alfa. A comparison between placebo/control and Sebelipase alfa will be made.

Article selection, data extraction, and analysis:
Three reviewers participated in the article selection process, which was conducted using the previously described inclusion and exclusion criteria. They also extracted data from the selected papers. Three stages of article selection—title, abstract, and full-text—were used in this meta-analysis investigation. Any dispute that arose during the study was settled by our guide and the three reviewers after they talked it out. The necessary information for our study, including the authors' methods, participant information, interventions, frequency or duration of treatment, parameters considered in the studies, outcome measures, and adverse effects, was extracted by each of the three reviewers from the included studies.
Some research reports only their findings graphically; therefore, to obtain numerical values, we used the built-in measurement tool in Adobe® Reader® XI, version 11.0.06 (Adobe Systems Incorporated, San Jose [California]), and Origin 8.6, the first 64-bit version, to extract numerical data from the graphs. Any differences were settled by talking with our guide and the other peer reviewers (the other two reviewers).

Statistical analysis:
The data were analyzed statistically using Review Manager (RevMan v. 5.4.1) and HDS Tools (Health Decision Strategies, LLC). A random-effects model with an odds ratio (OR) as the effect measure with a 95% confidence interval was used to estimate the Mantel-Haenszel (M-H) statistic for dichotomous variables, while the fixed-effects model with a mean difference (MD) or standardized mean difference (SMD) was used to estimate the inverse variance (IV) for continuous variables. Following the acquisition of forest plots, the I2 (I square) statistics were used to compute heterogeneity. This test's I2 statistic quantifies the proportion of variation in research results attributable to heterogeneity rather than sampling error. An I2 value that is less than 40% is regarded as unimportant, whilst an I2 value of greater than 40% is regarded as moderate to significant heterogeneity.

Table-1: Prisma flow chart of Sebelipase Alfa study selection criteria.



Sebelipase alfa Meta-analysis results:
In the Sebelipase alfa meta-analysis, 22 articles with 755 participants were selected for systematic review and meta-analysis from a total of 715 articles identified through the internet search. The accompanying table 1 shows the results of the PRISMA flow chart for the chosen investigations. The analysis was conducted using both prospective and retrospective research designs, and the table above summarizes the features of the included studies. Sebelipase alfa was used frequently across all included studies, and its safety and effectiveness were compared with the control group. Some of these studies included both standard treatment and Sebelipase alfa groups, indicating that participants had previously received or had a history of using other lipid-lowering medications, such as statins. One study also disclosed that the participants were undergoing Lipoprotein Apheresis, which is considered the standard of care (SOC). In these studies, the comparison was between Sebelipase alfa + SOC and SOC alone or placebo; therefore, SOC alone is considered a placebo. The mid-dose response was considered in the analysis of studies in which participants received repeated doses of Sebelipase alfa. This study compared the effects of Sebelipase alfa treatment versus control/SOC or placebo groups in patients with lysosomal acid deficiency [LALD]. The effectiveness parameters included LDL-C, Total Cholesterol, HDL, apolipoprotein B (Apo-B), Total Triglycerides, reductions in ALT and AST, and event rates such as weight gain, GI-related adverse effects, and more.

Quality assessment:
Every included study passed the quality evaluation and had a minimal risk of bias.

Efficacy Parameters:
When assessing and drawing conclusions about the effectiveness of Sebelipase Alfa, the following characteristics were taken into consideration: LDL-C, Total Cholesterol, HDL, Apo lipoprotein B (Apo-B), and Total Triglycerides were considered for evaluating in Lysosomal acid deficiency [LALD] patients

SI.No	Author (s) & Year	Study design	Total Patients (SA/Placebo)	Control Group (SOC/Placebo)	Treatment Group	Parameters Evaluated	References
1	Elmar Aigner, Alexandra Feldman et al., 2018	Case Report	1 (Female, Age 63)	NA	Sebelipase alfa ERT	Portal hypertension, atherosclerosis progression	[14]
2	Zareena Angamia et al., 2020	Case Report	1 (Female, Age 31)	NA	Ezetimibe 10 mg daily	Liver function tests and lipid profiles (TC, TG, LDL-C, and HDL-C)	[15]
3	D. Ashok, C. Prasad et al., 2018	Case Report	3 (2 Adults, 1 Child)	NA	Sebelipase alfa (1 mg/kg biweekly)	Liver enzymes, lipid profile, liver stiffness	[16]
4	Manisha Balwani, Catherine Breen et al., 2013	Phase 1/2 Open-Label, Dose Escalation	9 (SA)	NA	0.35, 1, or 3 mg/kg SA weekly	ALT, AST, TC, LDL-C, HDL-C, TG	[17]
5	Eric Bruckert, Sachin Marulkar et al., 2017	Prospective Study	NA	LLM vs No LLM	Sebelipase alfa up to 52 weeks	LDL-C, LDL-P number	[18]
6	Dominik Soll et al., 2019	Case Report	1 (Age 26)	NA	Sebelipase alfa IV biweekly	Early diagnosis, genetic testing	[19]
7	Thomas Grenkowitz, Nikolaus Buchmann et al., 2017	Case Report	1 (Female, Age 62)	NA	Sebelipase alfa + Lipid Apheresis	Lipid profile, hepatosplenomegaly, hepatic steatosis	[20]
8	Ilknur Kulhas Celik et al., 2018	Clinical Trial	3	NA	Desensitization protocol (SA)	Hypersensitivity reactions, desensitization success	[21]
9	S. Rojas-Caro et al., 2015	Phase 3, Double-Blind, Placebo-Controlled	66 (SA: 31%; PBO: 7%)	Placebo	1 mg/kg SA biweekly	ALT, non-HDL-C, LDL-C	[22]
10	S. Jones et al., 2006	Phase 2/3	9 Infants	NA	Sebelipase alfa	Growth parameters, disease activity, survival	[23]
11	U. Kassner et al., 2019	Case Report	1 (Age 20)	NA	Sebelipase alfa	Clinical symptoms, adverse effects	[24]
12	DP Wilson et al., 2017	Cohort Study	4	NA	Sebelipase alfa	LAL-D inheritance, LIPA mutation	[25]
13	Michelle F. Huffaker et al., 2019	Case Series	3	NA	Desensitization protocol	Hypersensitivity reactions, desensitization	[26]
14	Peter E. Thelwall et al., 2013	Prospective Study	NA	NA	Sebelipase alfa	Hepatic lipid signature, non-invasive diagnosis	[27]
15	Ermelinda Santos Silva et al., 2018	Case Report	2 Infants	NA	Sebelipase alfa	HLH progression, liver failure	[28]

16	Soumya Mula et al., 2019	Phases I, II, III	66	NA	Sebelipase alfa	Safety, liver function, dyslipidemia, survival	[29]
17	Suresh Vijay et al., 2021	Phase 2/3	NA	NA	Sebelipase alfa weekly	Growth, liver volume, spleen volume	[30]
18	Radhika Tripuraneni et al., 2013	Long-Term Study	NA	NA	Sebelipase alfa	Transaminases, lipid profile	[31]
19	Vera Malinova et al., 2020	Phase 2, Open-Label	8	NA	Sebelipase alfa	ALT, AST, lipid profile	[32]
20	Radhika Tripuraneni, Reena Sharma, Manisha Balwani et al., 2013	Phase 1/2	7 (SA)	NA	1 mg/kg or 3 mg/kg SA	Serum lipids, transaminases, liver fat	[33]
21	Suresh Vijay, Anais Brassier et al., 2021	Phase 2/3	NA	NA	Sebelipase alfa weekly	Survival, growth, psychomotor development	[34]
22	Vera Malinova, John Kane et al., 2020	Open-Label Extension	8 (SA)	NA	1.0 or 3.0 mg/kg SA biweekly	ALT, AST, lipid levels	[35]

LDL-C levels in Sebelipase Alfa studies:
Regarding lowering patients' LDL-C levels, the meta-analysis found a statistically significant difference between Sebelipase alfa and control/SOC therapies. The following are the outcomes (inverse variance, or IV): Sebelipase alfa is significantly lower at 95% CI -39.46 (-43.57, -35.35), p=<0.00001, I2 = 81%.The forest plot analysis for the effect of LDL-C levels is shown in Figure 1.

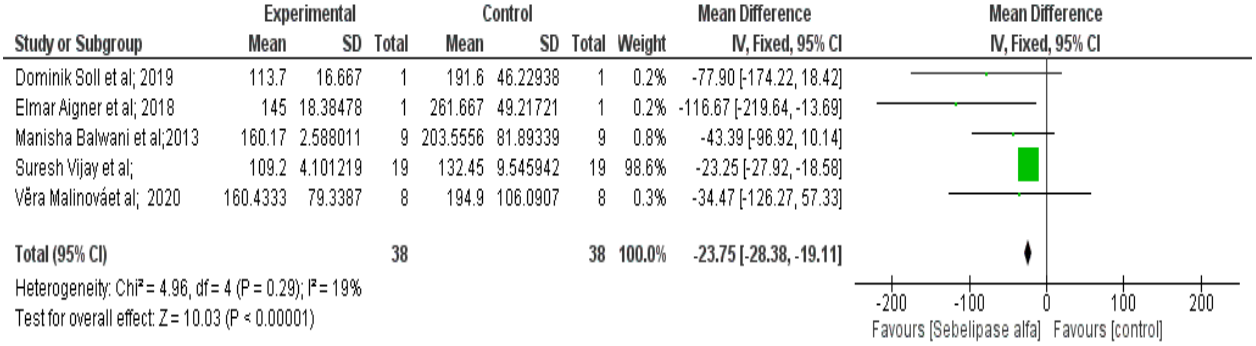


Figure-1 Effect of Sebelipase alfa on LDL-C levels

Total Cholesterol levels in Sebelipase Alfa studies:
According to the meta-analysis's findings, the Sebelipase alfa treatment group and the control/SOC group significantly differed in their ability to lower the patients' VLDL levels. This is demonstrated by the inverse variance (IV): -23.75 (-28.38,-19.11) at 95% CI, p=<0.00001, I 2 = 19%), indicating a significant reduction in total cholesterol levels with sebelipase alfa in figure 2.

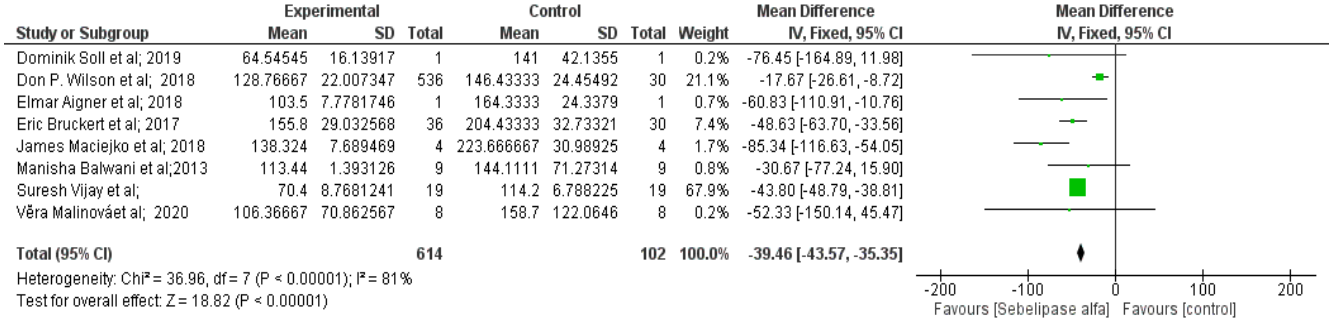


Figure-2 Effect of Sebelipase alfa on Total Cholesterol levels

HDL levels in Sebelipase Alfa studies:

According to the findings, a statistically significant difference has been found between the Sebelipase alfa treatment group and control/SOC group regarding a slight increase in HDL levels in the patients, as follows (inverse variance (IV):0.84 (0.61,1.07) at 95% Cl, p=<0.00001, I 2=94%). A significant increase in HDL levels is shown in figure-3

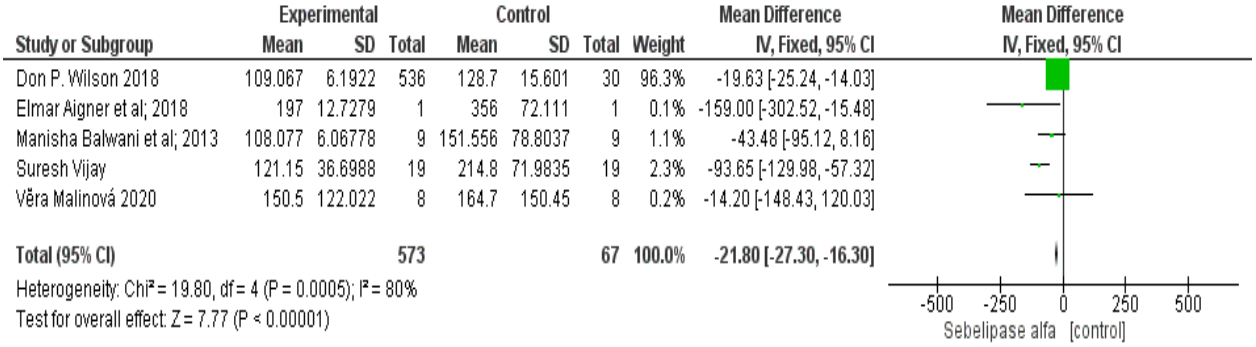


Figure-3 Effect of Sebelipase alfa on HDL levels

Total Triglycerides levels in Sebelipase Alfa studies:

The meta-analysis's findings demonstrated that the Sebelipase alfa treatment group and the control/SOC group differed statistically significantly in their ability to lower patients total triglyceride levels. This is explained by the inverse variance (IV): -21.80 (-27.30, -16.30) at 95% CI, p < 0.00001, I2 = 80%, indicating that Sebelipase alfa significantly lowers total triglyceride levels, as shown in Figure 4.

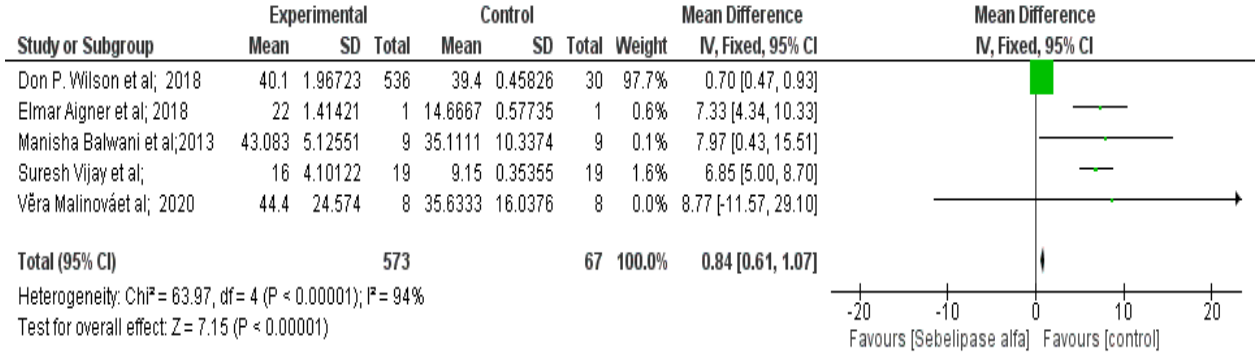


Figure-4 Effect of Sebelipase alfa on Total Triglycrides levels

Apo Lipoprotein-B in Sebelipase Alfa studies:

The results have demonstrated that a statistically significant difference was found between the Sebelipase alfa treatment group and control/SOC group regarding reducing the Apo lipoprotein-B levels in the patients, as follows (inverse variance (IV): -20.96 (-25.32,–16.61) at 95% CI, p=<0.00001, I 2 =97%). Concluding that Sebelipase alfa significantly reduces Apo-B levels, as shown in the forest plot (Figure 5).

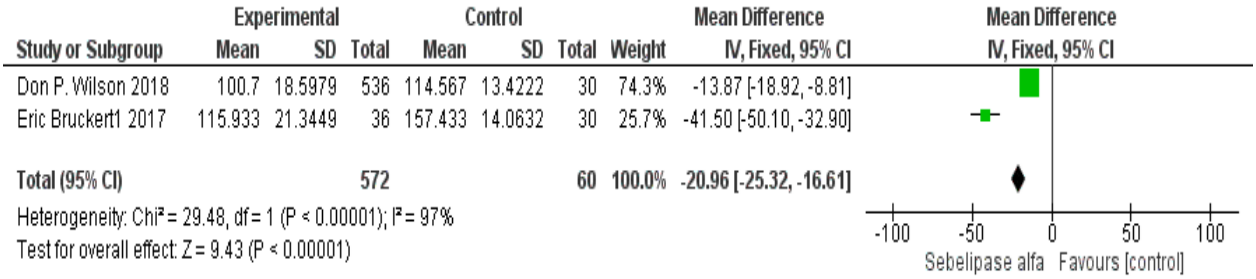


Figure-5 Effect of Sebelipase alfa on Apo Lipoprotein-B levels

ALT levels in Sebelipase Alfa studies:
The results of the meta-analysis demonstrated that the Sebelipase alfa and control/SOC groups differed statistically significantly (inverse variance (IV): -37.89 (-49.57, – 26.21) at 95% CI, p=<0.00001, I 2 = 27%), indicating that Sebelipase alfa significantly lowers ALT levels.

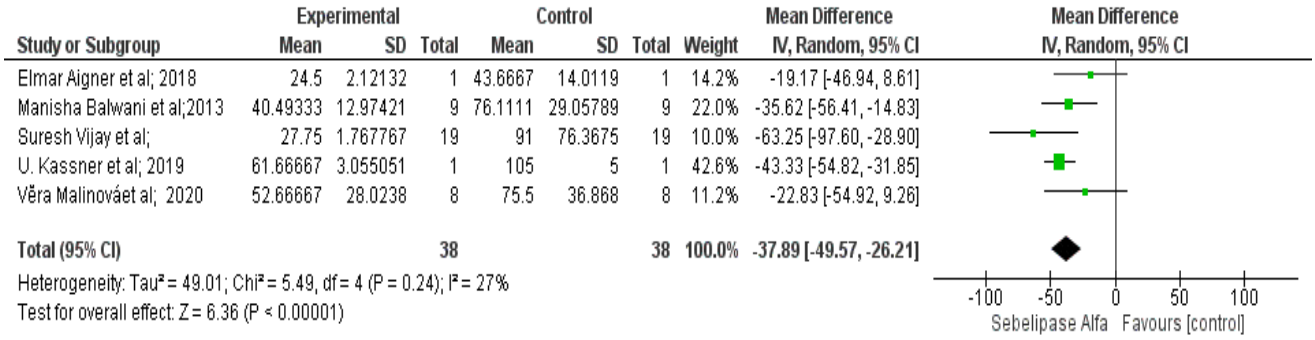


Figure-6 Effect of Sebelipase alfa on ALT levels

AST levels in Sebelipase Alfa studies:
The results showed a statically significant difference between the sebelipase alfa and the treatment group and control/SOC group regarding reducing the AST levels in the patients follows (inverse variance (IV): -26.97 (-31.19,–22.76) at 95% CI, p=<0.00001, I 2 =98%) indicates that Sebelipase alfa significantly reduces AST levels as forest plot shown in the figure-7.

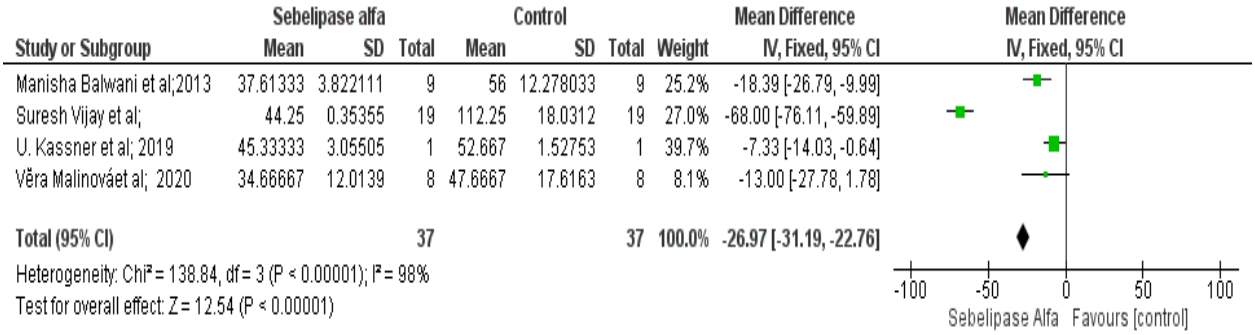


Figure-7 Effect of Sebelipase alfa on AST levels

Safety Parameters studied in Sebelipase Alfa:
When comparing the safety of Sebelipase alfa with the control group in patients with Lysosomal acid Lipase deficiency, parameters such as weight gain and Sebelipase alfa-induced gastrointestinal (GI) adverse events (e.g., diarrhoea, abdominal cramping, and nausea or vomiting) were considered.

Rate of weight gain caused by Sebelipase alfa: The analysis's findings showed that the group treated with sebelipase had a higher likelihood of gaining weight than the control/SOC group (M-H, RE-OR of 66.36 (1.80, 2444.55) at 95% CI, p=0.02, I 2 = 30).

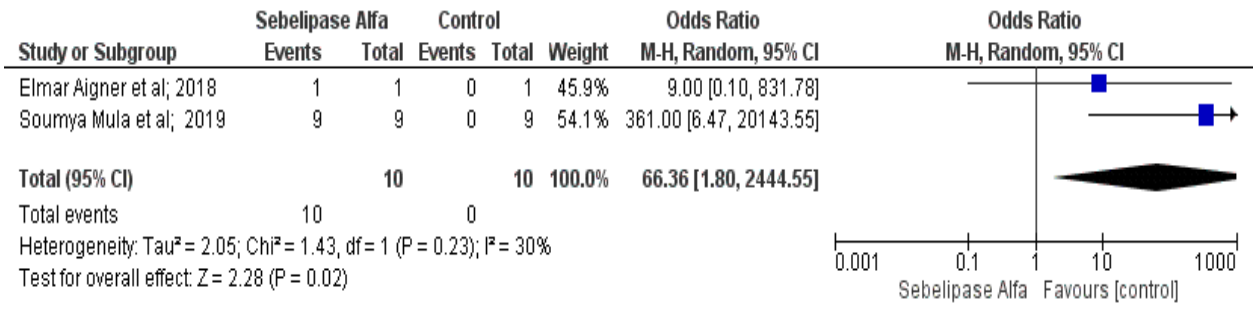


Figure-8 Incidence of Sebelipase alfa induced Weight gain

Incidence of Sebelipase alfa-induced gastrointestinal (GI) adverse events:
The analysis showed that the incidence of GI-related adverse events differed statistically significantly between the Sebelipase alfa-treated group and the control/SOC group, indicating that the former group was more likely to experience such events. At 95% CI, p=<0.00001, I2 = 0%, the random-effects odds ratio (RE-OR) was 19.38 (5.49, 68.33) (M-H).

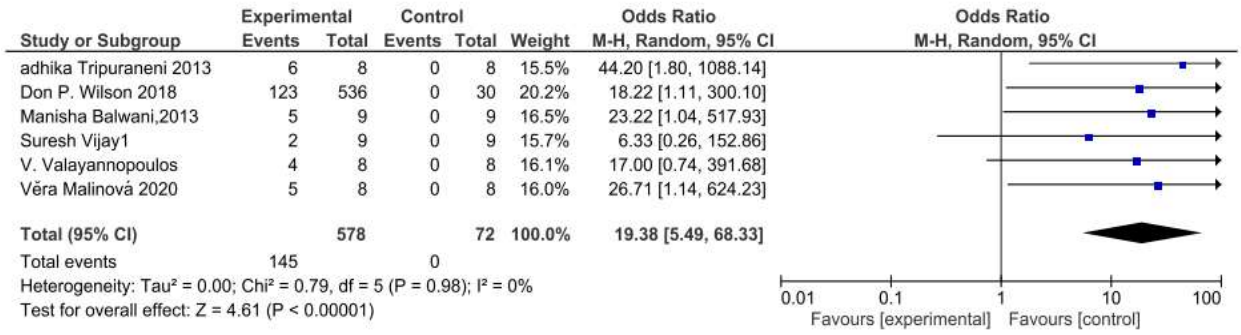


Figure 9: Incidence of Sebelipase alfa-induced gastrointestinal (GI) adverse events

DISCUSSION

SEBELIPASE ALFA: One of the lysosomal storage disorders is lysosomal acid lipase deficiency (LALD). Lysosomal acid lipase deficiency results in abnormal lipid metabolism, which can be lethal for both adult and paediatric patients. To regulate their lipid profiles, these patients were typically treated with additional lipid-lowering medications, such as statins and ezetimibe. To treat the condition, patients were given sebelipase alfa, a recombinant human lysosomal acid lipase, to replace the enzyme they lacked. Sebelipase alfa treatment reduced the frequency of lipoprotein apheresis (LA) in individuals receiving LA.

Sebelipase alfa, in combination with other lipid-lowering drugs or lipoprotein apheresis, or as a monotherapy, significantly lowers lipid profile values to normal levels, but the decision depends on the severity of the patient's condition. LDL-C, total cholesterol, HDL, apolipoprotein B (ApoB), total triglycerides, ALT, and AST are among the markers.

According to the meta-analysis's findings, giving Sebelipase alfa to LALD patients may help them lower their LDL-C levels. Five of the included trials provided total cholesterol (TC) as a criterion, and all five of them endorsed the use of sebelipase alfa to lower TC levels. It has been shown to be effective in lowering total triglyceride (TG) levels in individuals with LALD, according to all five included trials. All five trials that included HDL as a metric showed an increase in HDL levels after Sebelipase alfa treatment. Both included trials have shown support for the use of sebelipase alfa to lower Apo-B levels in patients with LALD. All five included studies analyzed for ALT Parameter 5 support the use of this to lower ALT levels. Overall, we may conclude that administering Sebelipase alfa would lower the elevated lipid profile and, with the exception of a rise in HDL levels, based on this meta-analysis of relatively certain evidence.

CONCLUSION

Sebelipase alfa significantly decreases lipid parameters such as LDL-C, Total Cholesterol, Total Triglycerides, Apo Lipoprotein-B, and increases HDL levels; it also reduces elevated ALT & AST levels. However, compared to the SOC/control group, participants treated with sebelipase alfa have a greater risk of experiencing negative outcomes such as weight increase and GI-related side effects.

Conflicts Of Interest:

There are no conflicts of interest for the authors.

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