

The Effect of the Ketogenic Diet on Weight Loss and Metabolic Risk Factors: A Systematic Review and Meta-Analysis

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Abstract

Obesity remains a major global health problem with increasing prevalence, leading to a rise in the use of dietary interventions such as the ketogenic diet. Despite its popularity, evidence regarding its effectiveness in improving metabolic parameters remains inconsistent. This study aimed to evaluate the impact of the ketogenic diet on weight loss and metabolic risk factors through a systematic review and meta-analysis. Following the PRISMA 2020 guidelines, relevant studies were retrieved from PubMed, ScienceDirect, Cochrane Library, and ProQuest databases. Eligible randomized controlled trials assessing the effects of the ketogenic diet on glucose control, blood pressure, body mass index (BMI), and lipid profiles in obese patients were included. Data extraction and quality assessment were conducted using the Risk of Bias (RoB) tool, and statistical analyses were performed with Review Manager v5.3. Nine eligible studies (n = 437 participants) were included. The ketogenic diet significantly reduced blood glucose levels (SMD = -0.27 mg/dL, 95% CI: -0.50 to -0.04, P = 0.02) and triglycerides (SMD = -28.38 mg/dL, 95% CI: -32.07 to -24.69, P < 0.001), while increasing LDL cholesterol (SMD = 17.27 mg/dL, 95% CI: 1.10 to 33.44, P = 0.04). However, no significant changes were observed in BMI, HDL, total cholesterol, or blood pressure. Funnel plot and Egger's test results indicated no publication bias. In conclusion, the ketogenic diet demonstrates beneficial effects on glucose regulation and triglyceride reduction but has limited efficacy for weight loss and may elevate LDL levels, warranting cautious clinical application in obesity management.

Keywords: Weight loss, diet, ketogenic, metabolic, obesity.

INTRODUCTION

Obesity is one of the health problems with an increasing prevalence every year worldwide (Di Cesare et al., 2019). In 2022, the global prevalence of obesity in the pediatric population increased fourfold to 8% compared to 1990, which was only 2% (World Health Organization, 2024). Prospectively, if no actions are taken to address this trend, the projected population suffering from obesity is expected to increase to 20% by 2030 (Hruby & Hu, 2015).

From a risk factor perspective, obesity is a multifactorial health condition influenced by genetics, socioeconomic status, environment, education, and lifestyle habits (Kerkadi et al., 2019). Lifestyle, which includes dietary patterns, is the most extensively studied factor and is a widely used strategy in obesity management because it is non-invasive and helps in long-term control (Hwalla & Jaafar, 2021). Consequently, various types of diets have been developed and studied to improve metabolic status and conditions associated with obesity, such as blood glucose levels, weight loss, body mass index, blood pressure, and lipid profiles (Stanciu et al., 2023; Du et al., 2023).

The ketogenic diet is one dietary method developed and has gained popularity in recent years as a dietary-based obesity management approach (Charlot & Zoll, 2022). As a dietary method for managing obesity, the ketogenic diet aims to aid in weight loss and the management of metabolic risk factors in obese patients. The ketogenic diet emphasizes reducing carbohydrate intake to below 10%, replacing it with high-fat and moderate-protein foods, thereby inducing the body into ketosis (Zhang et al., 2021). This condition prompts the body to use ketones derived from fat as an energy source (Gershuni et al., 2018).

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Several previous studies have explored the effects of the ketogenic diet on obesity management, but their results remain inconsistent due to variations in study duration, dietary composition, and participant characteristics. Bueno et al. (2013) conducted a meta-analysis and found that low-carbohydrate diets, including ketogenic diets, were more effective than low-fat diets in short-term weight loss and triglyceride reduction; however, the study was limited by heterogeneity in intervention periods and lacked detailed analysis of metabolic parameters such as LDL and HDL levels. Similarly, Choi et al. (2020) demonstrated that the ketogenic diet improved glycemic control and reduced body fat percentage in obese patients but noted a potential rise in LDL cholesterol and limited generalizability due to the small number of Asian participants.

Numerous studies have been conducted to examine the effectiveness of the ketogenic diet as a dietary-based management approach for obese patients. However, there remains inconsistency between the findings of different studies regarding the efficacy of the ketogenic diet. Therefore, this study aims to evaluate the effect of the ketogenic diet on weight loss and metabolic risk factors through a systematic review and meta-analysis design. The results are expected to assist clinicians and nutritionists in optimizing dietary recommendations for obese patients and contribute to the refinement of dietary-based interventions for metabolic health improvement.

METHOD

This systematic review and meta-analysis were conducted by identifying, assessing, and interpreting all findings related to the scientific topic. The authors used the PICOS (Population, Intervention, Comparison, Outcome, Studies) strategy to identify all relevant studies. All systematic search procedures were performed based on the 2020 Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) guidelines.

The studies included in this review were all articles sourced from online databases, including PubMed (MEDLINE), Science Direct, Cochrane Library, and ProQuest, which evaluated the effects of the ketogenic diet therapy on patients with obesity and/or metabolic syndrome. The obese population was defined as having a BMI ≥ 30 , while metabolic syndrome was defined as a cluster of conditions occurring simultaneously that increase the risk of heart disease, stroke, and type 2 diabetes. These conditions include a combination of high blood glucose levels, low HDL levels, high triglyceride levels, increased waist circumference due to fat accumulation, and high blood pressure.

The measured parameters included: 1) blood glucose levels (mg/dL) including fasting blood glucose, postprandial glucose, or random glucose levels; 2) body mass index; 3) systolic and diastolic blood pressure; 4) lipid profile (mg/dL) including cholesterol, triglycerides, high-density lipoprotein (HDL), and low-density lipoprotein (LDL) after the intervention of a ketogenic diet. The general population in this study comprised all individuals suffering from obesity and/or metabolic syndrome who underwent ketogenic diet therapy. The definition of the ketogenic diet used was a low-carbohydrate, high-fat diet intended to induce ketosis, a state where the body burns fat for energy instead of carbohydrates. The macronutrient ratio in the ketogenic diet was defined as 70-80% fat, 15-20% protein, and 5-10% carbohydrates from daily calories.

Studies were excluded if they: (1) involved populations receiving other treatments besides the ketogenic diet, (2) had a follow-up period of less than one month, (3) did not include parameters for weight loss or metabolic syndrome risk factors, (4) had an observational study design, (5) were published more than 5 years ago.

The literature search for relevant studies used a number of keywords developed from PICOS to obtain maximum search results. In the study search process, the authors' first step was to determine keywords using Medical Subject Headings (MeSH). After selecting keywords

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using MeSH, the authors conducted research journal searches using advanced search techniques, bibliography searches, and Boolean operators (AND, OR, and NOT) with keywords tailored to the research topic. The search terms used were as follows:

“(((MeSH] diet, ketogenic) OR (keto)) AND (([MeSH] obesity) OR ([MeSH] metabolic syndrome))”

Overall, this study used critical appraisal to assess the quality of articles that could be included in the systematic review. The authors independently performed data extraction. The quality assessment of the studies was conducted using RoB 2: A revised Cochrane risk-of-bias tool for randomized trials, which consists of five assessment domains: bias arising from the randomization process, bias due to deviations from intended interventions, bias due to missing outcome data, bias in outcome measurement, and bias in the selection of the reported result. Each domain was evaluated and given a risk of bias rating (low, some concerns, or high), which was then used to assess the overall risk of bias for the randomized controlled trials (RCTs). If the overall interpretation was satisfactory, the article was deemed to meet the criteria and included in the inclusion criteria, and vice versa.

Data analysis was conducted by systematically integrating and describing all data to draw conclusions. The data included study characteristics (lead author's name, publication year, study location, follow-up duration, intervention protocol, and population size), population characteristics (age and gender characteristics, and main study outcomes). The data were presented in tabular form (synthesis matrix) to facilitate analysis. Quantitative analysis was performed using mean difference analysis to determine parameter differences between the two groups, using Review Manager v.5.4 software. Heterogeneity was assessed using the I-squared and T-squared tests. A significant heterogeneity value indicated the use of a random effects model in the analysis, while a low heterogeneity value indicated the use of a fixed effects model. The risk of publication bias was assessed using a funnel plot approach qualitatively and Egger's test quantitatively. A significant p-value was considered to be <0.05.

RESULTS AND DISCUSSION

Study Search

In the study search process, a total of 5093 articles were obtained from databases (PubMed, ScienceDirect, Cochrane, and ProQuest). After removing duplicates using citation management software, 5071 articles remained. During the title and abstract screening process, 27 accessible articles were identified and subsequently assessed for eligibility. Further, 18 articles were excluded due to incomplete or relevant data on outcome results after ketogenic diet therapy, leading to qualitative (systematic review) and quantitative (meta-analysis) analyses using 9 included studies. The study search flow using the PRISMA guidelines is depicted in Figure 1.

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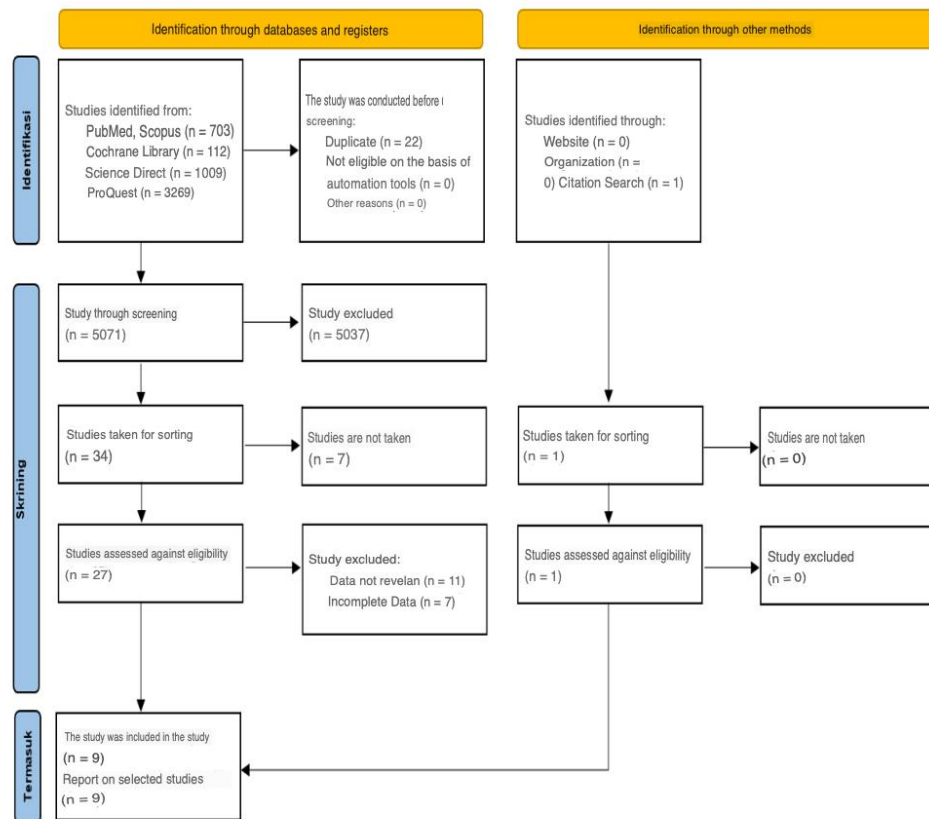


Figure 1. PRISMA Flowchart

Characteristics of Studies

This study included a total of 9 randomized controlled trials, with the majority of studies originating from China (four studies), followed by Italy and the United States, each with two studies, and one study from Spain. The total number of patients involved in these studies was 437. Regarding the age groups in the research, the average age of patients undergoing the ketogenic diet ranged from 20.8 to 60.5 years, while the average age of patients in the control group ranged from 21.6 to 64.4 years. The majority of the study population consisted of patients with obesity and co-existing conditions such as type 2 diabetes mellitus, PCOS, liver dysfunction, and obstructive sleep apnea. The overall characteristics of the studies can be seen in Table 1.

Table 1. Study Characteristics

No.	Lead Author, Year	Study Type	Country	Characteristics of Studies		Intervention Duration	Characteristics of Samples		
				Treatment	Control		Mean Age of Treatment Group (years)	Mean Age of Control Group (years)	Sample Population
1.	Hall et al., 2021 ¹¹	RCT	USA	Animal-based, ketogenic diet	Plant-based, low-fat diet	4 weeks	N/A	N/A	Overweight patients
2.	Li et al., 2021 ¹²	RCT	China	Ketogenic diet	Polyene phosphatidylcholine capsule	12 weeks	31,13	28,9	Female PCOS patients with obesity and liver dysfunction
3.	Li et al., 2022 ¹³	RCT	China	Ketogenic diet	Diet diabetes	12 weeks	36,5	37,1	Type 2 diabetes mellitus (T2DM) patients with obesity
4.	Li et al., 2023 ¹⁴	RCT	China	Ketogenic diet	Diet diabetes	8 weeks	37,8	37,4	Type 2 diabetes mellitus (T2DM) patients with obesity
5.	Moriconi et al., 2020 ¹⁵	RCT	Italy	Very-low-calorie ketogenic diet	Low-calorie diet	3 months	60,5	64,4	Type 2 diabetes mellitus (T2DM) patients with obesity
						12 months			

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No.	Lead Author, Year	Study Type	Country	Characteristics of Studies			Characteristics of Samples		
				Treatment	Control	Intervention Duration	Mean Age of Treatment Group (years)	Mean Age of Control Group (years)	Sample Population
6.	Sanchez et al., 2021 ¹⁶	RCT	Spain	<i>Very low-calorie ketogenic diet</i>	<i>Mediterranean diet</i>	24 weeks	40,7	39,7	Patients with moderate obesity
7.	Saslow et al., 2023 ¹⁷	RCT	USA	<i>Very-low carbohydrate</i>	<i>Dietary Approach to Stop Hypertension</i>	16 weeks	60,09	58,4	Hypertensive and T2DM/prediabetes patients with obesity
8.	Schiavo et al., 2022 ¹⁸	RCT	Italy	<i>Continuous positive airway pressure + Low-calorie ketogenic diets</i>	<i>Continuous positive airway pressure</i>	16 weeks	N/A	N/A	Severe obstructive sleep apnea patients with obesity
9.	Sun et al., 2019 ¹⁹	RCT	China	<i>Low-calorie intake control</i>	<i>Normal diet</i>	4 weeks	20,9	21,6	Overweight women
				<i>Low-calorie intake + high-intensity interval training group</i>			20,8	21,6	
				<i>Low-calorie intake + moderate-intensity continuous training group</i>			21,5	21,6	

Study Outcomes

Tabel 2. Study Outcomes

Authors, Year	Study Outcomes	Risk of Bias
Hall et al., 2021 ¹¹	An animal-based ketogenic diet showed an insignificant improvement in blood sugar levels compared to a plant-based low-fat diet. However, a plant-based low-fat diet showed a significant improvement in lipid profiles compared to an animal-based ketogenic diet.	Low risk
Li et al., 2021 ¹²	A ketogenic diet has effects on improving blood glucose levels and body weight, enhancing liver function, and addressing fatty liver compared to traditional pharmacological treatments.	Low risk
Li et al., 2022 ¹³	A periodically conducted ketogenic diet can control body weight, blood glucose levels, and lipid profiles.	Low risk
Li et al., 2023 ¹⁴	A ketogenic diet administered twice daily is effective in controlling body weight, blood glucose, and lipid profiles in obese T2DM patients.	Low risk
Moriconi et al., 2020 ¹⁵	A very low-calorie ketogenic diet is effective and safe in managing obesity.	Moderate risk
Sanchez et al., 2021	A very low-calorie ketogenic diet can significantly lower blood pressure and reduce BMI.	Low risk
Sanchez et al., 2021 ¹⁶	A ketogenic diet or very low-calorie diet shows significant improvements in blood pressure, glycemic control, and body weight.	Low risk
Saslow et al., 2023 ¹⁷	The administration of a ketogenic diet with CPAP has significant effects on controlling lipid profiles, body weight, and blood pressure in obese patients with severe obstructive sleep apnea.	Low risk
Schiavo et al., 2022 ¹⁸	A ketogenic diet has a significant impact on improving body weight and body composition, but the addition of physical activity does not show significant improvements.	Low risk

Risk of Bias Analysis

Overall, most of the included studies, except for two, showed a low risk of bias across all domains, indicated by green boxes. The studies by Saslow et al., 2023, and Sanchez et al., 2021, had domains with unclear risk of bias (blinding of participants and personnel, and blinding of outcome assessment), indicated by yellow boxes. The comprehensive risk of bias analysis of the included studies is shown in Figure 2.

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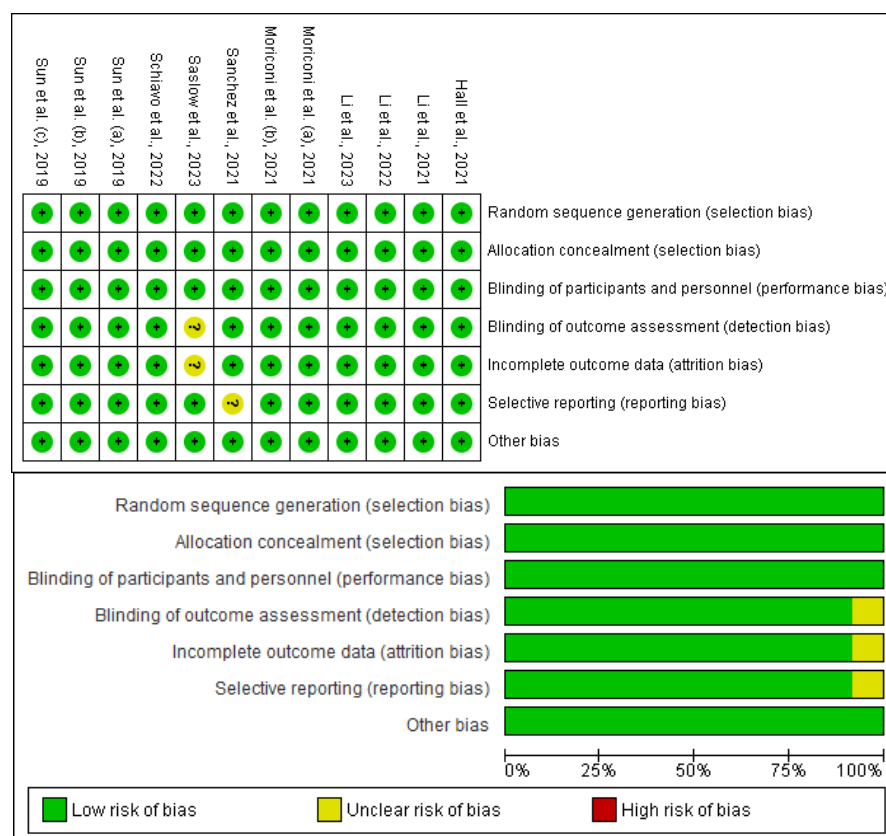


Figure 2. Risk of Bias Analysis of Included Studies (top) by Each Domain and (bottom) Overall

Quantitative Analysis

A total of 6 studies were included in the blood glucose parameter analysis. Based on the analysis results, the overall effect of the ketogenic diet compared to the comparator had a significant standardized mean difference (SMD) of -0.27 mg/dL (95% CI: -0.50, -0.04; $P = 0.02$), indicating that the ketogenic diet had a slightly better effect. No significant heterogeneity was observed among these studies ($\text{Chi}^2 = 7.53$, $\text{df} = 8$, $P = 0.48$; $I^2 = 0\%$) (Figure 3a).

A total of 7 studies were included in the BMI parameter analysis. Based on the analysis results, the overall effect of the ketogenic diet compared to the comparator had a non-significant mean difference (MD) of -0.65 (95% CI: -1.88, 0.58; $P = 0.2$), indicating that the ketogenic diet had a slightly better effect. No significant heterogeneity was observed among these studies ($\text{Chi}^2 = 17.76$, $\text{df} = 9$, $P = 0.04$; $I^2 = 49\%$) (Figure 3b).

A total of 4 studies were included in the systolic blood pressure parameter analysis. Based on the analysis results, the overall effect of the ketogenic diet compared to the comparator had a non-significant standardized mean difference (SMD) of -0.54 mmHg (95% CI: -1.42, 0.34; $P = 0.23$), indicating that the ketogenic diet had a slightly better effect. No significant heterogeneity was observed among these studies ($\text{Chi}^2 = 32.20$, $\text{df} = 4$, $P < 0.001$; $I^2 = 88\%$) (Figure 3c).

A total of 2 studies were included in the diastolic blood pressure parameter analysis. Based on the analysis results, the overall effect of the ketogenic diet compared to the comparator had a non-significant standardized mean difference (SMD) of -0.27 mmHg (95% CI: -1.05, 0.52; $P = 0.50$), indicating that the ketogenic diet had a slightly better effect. No significant heterogeneity was observed among these studies ($\text{Chi}^2 = 8.77$, $\text{df} = 2$, $P = 0.01$; $I^2 = 77\%$) (Figure 3d).

A total of 7 studies were included in the blood cholesterol parameter analysis. Based on the analysis results, the overall effect of the ketogenic diet compared to the comparator had a non-significant mean difference (MD) of 7.75 mg/dL (95% CI: -11.71, 27.21; $P = 0.44$),

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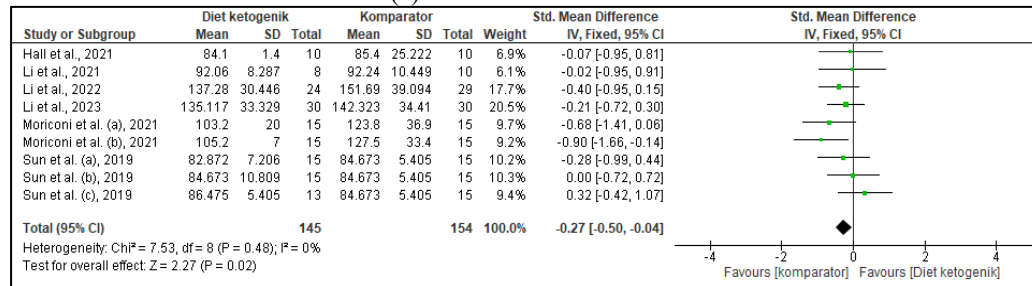
indicating that the ketogenic diet had a slightly better effect. No significant heterogeneity was observed among these studies ($\text{Chi}^2 = 21.59$, $\text{df} = 9$, $P < 0.001$; $I^2 = 96\%$) (Figure 3e).

A total of 6 studies were included in the blood triglyceride parameter analysis. Based on the analysis results, the overall effect of the ketogenic diet compared to the comparator had a significant mean difference (MD) of -28.38 mg/dL (95% CI: -32.07 , -24.69 ; $P < 0.001$), indicating that the ketogenic diet had a slightly better effect. No significant heterogeneity was observed among these studies ($\text{Chi}^2 = 8.84$, $\text{df} = 7$, $P = 0.26$; $I^2 = 21\%$) (Figure 3f).

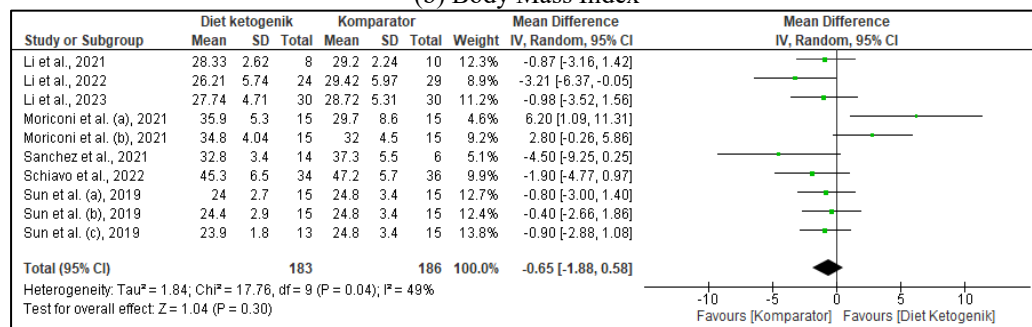
A total of 7 studies were included in the blood HDL parameter analysis. Based on the analysis results, the overall effect of the ketogenic diet compared to the comparator had a non-significant mean difference (MD) of -4.04 mg/dL (95% CI: -11.68 , 3.60 ; $P = 0.3$), indicating that the ketogenic diet had a slightly better effect. No significant heterogeneity was observed among these studies ($\text{Chi}^2 = 26.68$, $\text{df} = 9$, $P < 0.001$; $I^2 = 96\%$) (Figure 3g).

A total of 7 studies were included in the blood LDL parameter analysis. Based on the analysis results, the overall effect of the ketogenic diet compared to the comparator had a significant mean difference (MD) of 17.27 mg/dL (95% CI: 1.10 , 33.44 ; $P = 0.04$), indicating that the ketogenic diet had a slightly better effect. No significant heterogeneity was observed among these studies ($\text{Chi}^2 = 148.77$, $\text{df} = 9$, $P < 0.001$; $I^2 = 98\%$) (Figure 3h).

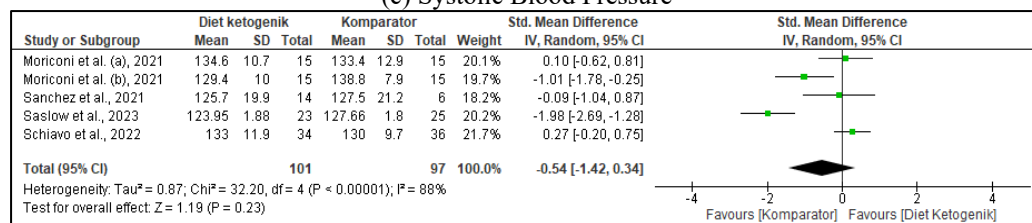
(a) Blood Glucose Levels



(b) Body Mass Index

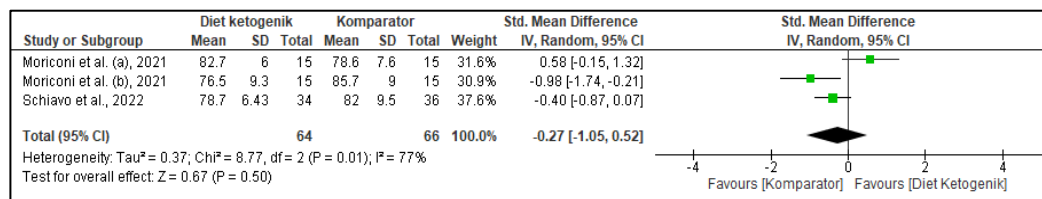


(c) Systolic Blood Pressure

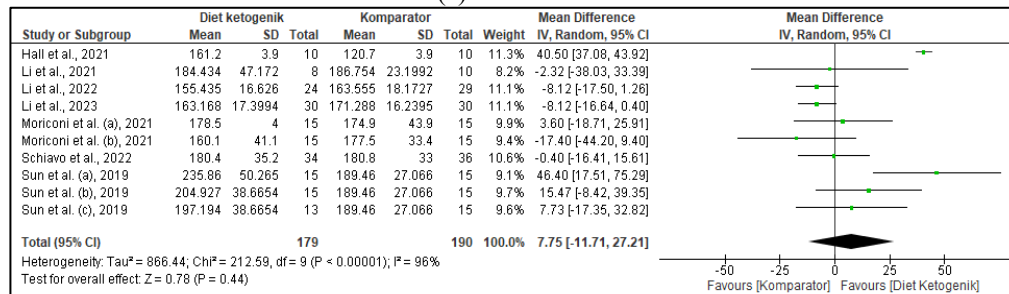


(d) Diastolic Blood Pressure

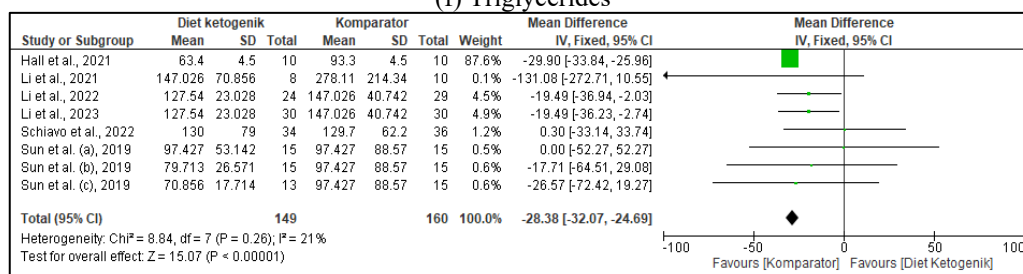
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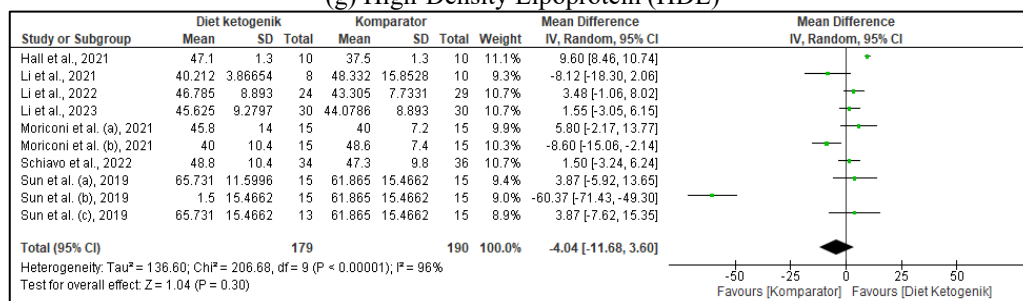
(e) Cholesterol



(f) Triglycerides



(g) High-Density Lipoprotein (HDL)



(h) Low-Density Lipoprotein (LDL)

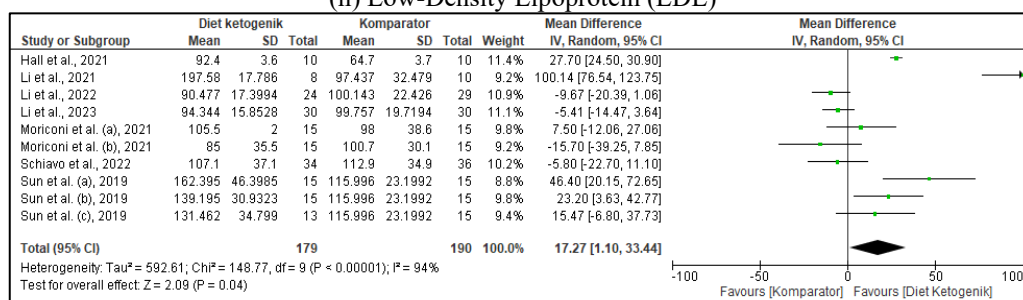


Figure 3. Forest Plot Analysis for Several Parameters Following Ketogenic Diet Intervention

Publication Bias

The Funnel Plot results indicate that the points representing the included studies are symmetrically distributed around the overall average effect value. This symmetrical visualization suggests a low likelihood of publication bias in this analysis. Furthermore, based on the quantitative analysis using Egger's test, a low risk of publication bias ($p > 0.05$) was

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found in all the parameter analyses obtained from the studies.

Funnel Plot Analysis for Parameters (a) Blood Glucose Levels; (b) Body Mass Index; (c) Systolic Blood Pressure; (d) Diastolic Blood Pressure; (e) Cholesterol; (f) Triglycerides; (g) High Density Lipoprotein (HDL); and (h) Low Density Lipoprotein (LDL) After the Ketogenic Diet Intervention.

Discussion

Metabolic syndrome is a condition comprising a cluster of issues including central obesity, dyslipidemia, hypertension, insulin resistance, and hyperglycemia. These conditions are risk factors for more severe health problems such as heart disease, stroke, type 2 diabetes, and others (Du et al., 2023). Globally, there has been a significant annual increase in individuals experiencing metabolic syndrome as a whole or one of its health issues. This is often linked to unhealthy behaviors or lifestyles, one of which is related to the food consumed (Gershuni et al., 2018).

The ketogenic diet is a dietary method developed for managing patients with obesity. This diet involves regulating the proportion of consumed foods, utilizing a composition of 70-80% fat from total daily calories, 20-25% protein, and only 5-10% carbohydrates (approximately equivalent to 50 grams of carbohydrates per day). This dietary composition causes the body to switch its main energy source from glucose to ketones produced through the lipolysis of fats, thereby reducing body fat. Several studies have demonstrated the efficacy of the keto diet in controlling blood sugar levels, weight loss, regulating blood pressure, and improving lipid profiles (Gershuni et al., 2018).

Based on the analysis in this study regarding the effects of the ketogenic diet on controlling glucose levels, it was found that the ketogenic diet significantly lowers blood glucose levels better than the control group receiving other dietary methods. Compared to previous meta-analysis studies conducted by Zhou et al. (2022), this study presents different results. Zhou et al. (2022) study did not find a significant reduction in glucose levels in the sample population receiving the ketogenic diet compared to the control group.²⁰ In this study, all included studies consistently showed a reduction in glucose levels in patients receiving the ketogenic diet.

Regarding body mass index (BMI), this study did not find a significant reduction in BMI between the group receiving the ketogenic diet and the control group. Similar findings were reported in previous meta-analysis studies by Zhou et al. (2022), although their study reported a higher mean difference than the findings of this study. In a deeper analysis of the included studies in this research, the study conducted by Moriconi et al. (2020) reported findings that the group receiving the ketogenic diet had a higher BMI compared to the control group. This is likely due to a significant baseline BMI difference between the ketogenic diet group and the control group, where the control group had a lower mean BMI than the ketogenic diet group. However, regarding changes in BMI in both groups, the group receiving the ketogenic diet experienced a significantly higher BMI reduction compared to the control group.

One of the targets in managing obesity and metabolic syndrome is the improvement or regulation of blood pressure. Increased blood pressure in patients with metabolic syndrome can be caused by various factors such as increased blood viscosity or structural disorders in blood vessels caused by long-term hyperglycemia and dyslipidemia (Saslow et al., 2023). Based on the analysis, this study found that the ketogenic diet did not show significant blood pressure improvement compared to the control group. In the analysis of included studies, there were clear inconsistencies in blood pressure parameters. In systolic blood pressure, studies by Moriconi et al. (2020) and Schiavo et al. (2022) found that by the end of treatment, the mean systolic blood pressure of patients on the ketogenic diet was higher than those on the control diet. This affects the analysis results in two ways: the small number of included studies on

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systolic blood pressure and the large sample proportion in both studies leading to insignificant findings.

As a diet focusing on reducing carbohydrate intake and replacing the main energy source with fats, the ketogenic diet appears to show a lower trend in reducing or regulating dyslipidemia compared to the control diet. In the analysis of total cholesterol variables, no mean difference was found at the end of the intervention between the ketogenic diet group and the control group. On the other hand, the analysis of triglycerides and LDL variables found significant differences. These findings are confirmed by previous meta-analysis studies by Zhou et al. (2022), which found that the ketogenic diet did not significantly affect total cholesterol and LDL reduction but agreed with the findings that the ketogenic diet significantly reduced mean triglyceride levels at the end of the treatment. Regarding HDL levels, the expected outcome is a significant increase with the ketogenic diet. However, this study did not find a significant difference in the increase of HDL levels between the ketogenic diet group and the control group.

This study has several limitations. Firstly, there are inconsistencies in findings among various studies, such as the difference between this research and previous meta-analyses on the ketogenic diet's impact on glucose levels. While this study consistently showed glucose reduction with the ketogenic diet, there was no significant BMI reduction, and some studies reported higher BMI in the ketogenic group due to initial differences. This highlights the need for more controlled studies with homogeneous baseline characteristics. These limitations suggest that although the ketogenic diet is promising, its effects on various components of metabolic syndrome require further investigation with more rigorous and standardized methodologies.

CONCLUSION

The ketogenic diet does not demonstrate significant efficacy in reducing body weight as evaluated through Body Mass Index (BMI) and blood pressure. However, the ketogenic diet significantly influences the control of glucose levels and lipid profiles in obese patients. Further studies are needed with controlled baseline parameters to avoid bias in the resulting research outcomes.

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