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REVIEW

Impact of Endoscopic Sleeve Gastroplasty in Non-alcoholic Fatty Liver Disease: a Systematic Review and Meta-analysis

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Abstract

Non-alcoholic fatty liver disease (NAFLD) is the most common cause of liver disease worldwide. Endoscopic sleeve gastroplasty (ESG) has proven to be feasible, safe, and effective in the management of obesity. We performed the first systematic review and meta-analysis evaluating NAFLD and other metabolic parameters 12 months post-ESG. Four

Key Points

- Non-alcoholic fatty liver disease (NAFLD) is the most common cause of hepatic disease increasing alongside obesity and diabetes mellitus. Initial treatment includes weight loss achieved through lifestyle intervention and diet, which are largely ineffective, with poor sustained weight loss.
- Endoscopic sleeve gastroplasty (ESG) is a reasonable alternative in treating NAFLD since it improves liver steatosis parameters, provides satisfactory weight loss, and reduces HbA1c levels after at least 12 months of follow-up.
- Although ESG is not yet approved by IFSO, its effectiveness and safety profile, at least in short-term follow-up has been proved by several studies and recognized by different renowned societies.
- Despite its effectiveness and safety, ESG cannot be compared to surgical outcomes, which is still the gold-standard method for obesity and its related comorbidities, including NASH.

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observational studies with a total of 175 patients were included. The results showed a significant ($p < 0.05$) reduction of 4.85 in hepatic steatosis index (95% CI − 6.02, − 3.67), 0.5 in NAFLD fibrosis score (95% CI − 0.80, − 0.19), 6.32 U/l in ALT (95% CI − 9.52, − 3.11), 17.28% in TWL (95% CI − 18.24, − 16.31), 6.31 kg/m^2 in BMI (95% CI − 8.11, − 4.52), 47.97% in EWL (95% CI − 49.10, − 46.84), and 0.51% in HbA1c (95% CI − 0.90, − 0.12). ESG improves liver parameters, provides weight loss, and reduces HbA1c levels in patients suffering from NAFLD.

Keywords Endoscopic sleeve gastroplasty · ESG · NAFLD · Obesity · Fatty liver disease · Bariatric

Introduction

Non-alcoholic fatty liver disease (NAFLD) is the most common cause of hepatic disease worldwide, with prevalence ranging from 25 to 45%, increasing alongside obesity and type 2 diabetes mellitus (T2DM). According to the Centers for Disease Control and Prevention, the prevalence of obesity among adults in the USA was approximately 42.4%, a significant public health concern. Additionally, around 73.6% of adults were classified as overweight or obese. NAFLD pathology was first described in 1980 and is divided into histological categories, including isolated hepatic steatosis, non-alcoholic steatohepatitis (NASH), and hepatocellular injury with or without fibrosis [1–3].

There are several risk factors related to non-alcoholic steatohepatitis and cirrhosis including the presence of metabolic syndrome, characterized primarily by central obesity, hypertension, insulin resistance (IR), high level of triglycerides, and low level of high-density lipoprotein cholesterol. Patients diagnosed with NAFLD have an increased risk of mortality up to 13% from complications related to liver disease, 25% from cardiovascular disease, and 28% from malignancy, predominantly hepatocellular carcinoma (HCC) [4, 5].

The main treatment for NAFLD is weight loss achieved through lifestyle intervention (LI) and diet. However, these non-invasive treatments are largely ineffective, with poor sustained weight loss usually failing to achieve 5% total weight loss (%TWL) [6]. Alternative therapies are considered for patients who do not meet weight loss goals after 6 months, including medications and endoscopic bariatric and metabolic therapies (EBMTs). Despite new medications showing better results, the continuous use and high costs turn it unfeasible for the majority of patients. EBTMs are a reasonable alternative since they are less invasive than bariatric surgery and have shown more consistent results than conservative treatments [7–9].

Endoscopic sleeve gastroplasty (ESG) is a minimally invasive technique that involves remodeling the stomach through the placement of full-thickness sutures reducing gastric capacity and delaying gastric emptying. ESG has been demonstrated to be technically feasible, safe, and effective in the management of overweight and obesity in various clinical settings around the world. Recently, several studies have reported promising results in terms of metabolic parameter improvement [10]. Therefore, to better understand the role of ESG in the management of NAFLD, we performed a systematic review and meta-analysis, evaluating liver steatosis biomarkers and other non-liver metabolic parameters, such as obesity and T2DM.

Materials and Methods

Protocol and Registration

This systematic review and meta-analysis were performed in conformity with the recommendations from the Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) guidelines [11]. The study protocol was registered in the International Prospective Register of Systematic Reviews (PROSPERO) database (https://www.crd.york.ac.uk/prospero/) under the file number CRD42023395849 and was approved by the Ethics Committee of Hospital das Clínicas, Faculty of Medicine at the University of São Paulo.

Search Strategy and Data Collection

Three authors individually conducted a systematic review of the literature by searching the following electronic databases: MEDLINE, EMBASE, Cochrane, and Google Scholar. The search was performed from inception to January 2023, without language or study design restrictions, using the mesh terms: ("Gastroplasty" OR "Bariatric Surgery") AND ("Endoscopy" OR "Endoscopic") AND ("Non-alcoholic Fatty Liver Disease" OR "nonalcoholic fatty liver disease" OR "non-alcoholic fatty liver disease*" OR "NAFLD" OR "hepatic steatosis" OR "fatty liver" OR "non-alcoholic steatohepatitis" OR "liver" OR "hepatic" OR "liver function test").

Disagreements regarding final study inclusion or data abstraction were resolved by consensus between 2 reviewers. If disagreement persisted, the first and senior authors were consulted. The reviewers independently conducted data abstraction onto a standardized spreadsheet that was designed in advance. The following data were collected

from the included studies: study characteristics (author, year of publication, country, study design, and the number of patients), patient demographics (mean age and body mass index (BMI) before ESG, percentage of female patients, and comorbidities), follow-up period, and outcomes. Corresponding authors were contacted for additional information if needed.

Eligibility Criteria and Outcomes

Studies were eligible for inclusion if they assessed the effect of ESG on patients suffering from overweight or obesity with a minimum of 12 months of evaluation including NAFLD scores. For double-arm studies, only data from the ESG group were included in the analysis. Only published articles with more than 10 patients were included without restrictions on language or publication year.

The primary outcome was the change in liver fibrosis, defined by NAFLD fibrosis score (NFS) and hepatic steatosis index (HSI). Secondary outcomes were the changes in liver enzymes, including alanine aminotransferase (ALT), and non-liver metabolic parameters, as %TWL, BMI, % excess weight loss (%EWL), and glycated hemoglobin A1c (HbA1c).

Risk of Bias and Evidence Quality

The risk of bias was assessed by the Risk of Bias in Non-randomized Studies of Interventions (ROBINS-I) tool [12]. The quality of evidence was expressed as high, moderate, low, and very low, utilizing the objective criteria from the Grading Recommendations Assessment, Development, and Evaluation, utilizing the GRADE pro-Guideline Development Tool software [13].

Statistical Analysis

Outcomes were reported as continuous variables, mean values, and standard deviations (SD). Results were expressed as median and interquartile range; the McGrath method was used for data conversion to means and SD [14]. The data of interest extracted from the selected studies were meta-analyzed using intention-to-treat analysis with the RevMan software (Review Manager Software version 5.4-Cochrane Collaboration Copyright© 2020). The mean values of each continuous outcome were calculated with a 95% confidence interval (CI). $P < 0.05$ were considered statistically significant, and the results were exposed through forest plots. Heterogeneity was calculated using the Higgins method (I^2) [15]. When heterogeneity $\leq 50\%$, the fixed-effect model was used. In heterogeneity $> 50\%$, random effect model was performed.

Results

Study Selection and Characteristics

A total of 4913 potential studies were identified. After title and abstract evaluation, 36 articles were selected for full-text review. A total of four prospective studies [16–19] were included based on the eligibility criteria (Tables 1 and 2).

Risk of Bias and Quality of Evidence

All studies [16–19] had an overall moderate risk of bias by the ROBINS-I tool (Fig. 1). The quality of evidence assessed by GRADE revealed a moderate certainty of evidence in all evaluated outcomes, except for HbA1c, resulting in a low certainty of evidence (Table 3).

Meta-analysis

Primary Outcomes

Non-alcoholic Fatty Liver Disease Fibrosis Score (NFS)

Three studies [17–19], including a total of 159 patients, reported the effect of ESG on liver steatosis using NFS. One-year post-ESG, the NFS reduced by a mean of 0.5 (95% CI − 0.80 to − 0.19; $I^2 = 12\%$; $P < 0.01$) (Fig. 2).

Hepatic Steatosis Index (HSI)

All studies [16–19], including a total of 175 patients, reported the effect of ESG on liver steatosis using HSI. One-year post-ESG, HSI reduced by a mean of 4.85 (95% CI − 6.02 to − 3.67; $I^2 = 44\%$; $P < 0.01$ (Fig. 3).

Secondary Outcomes

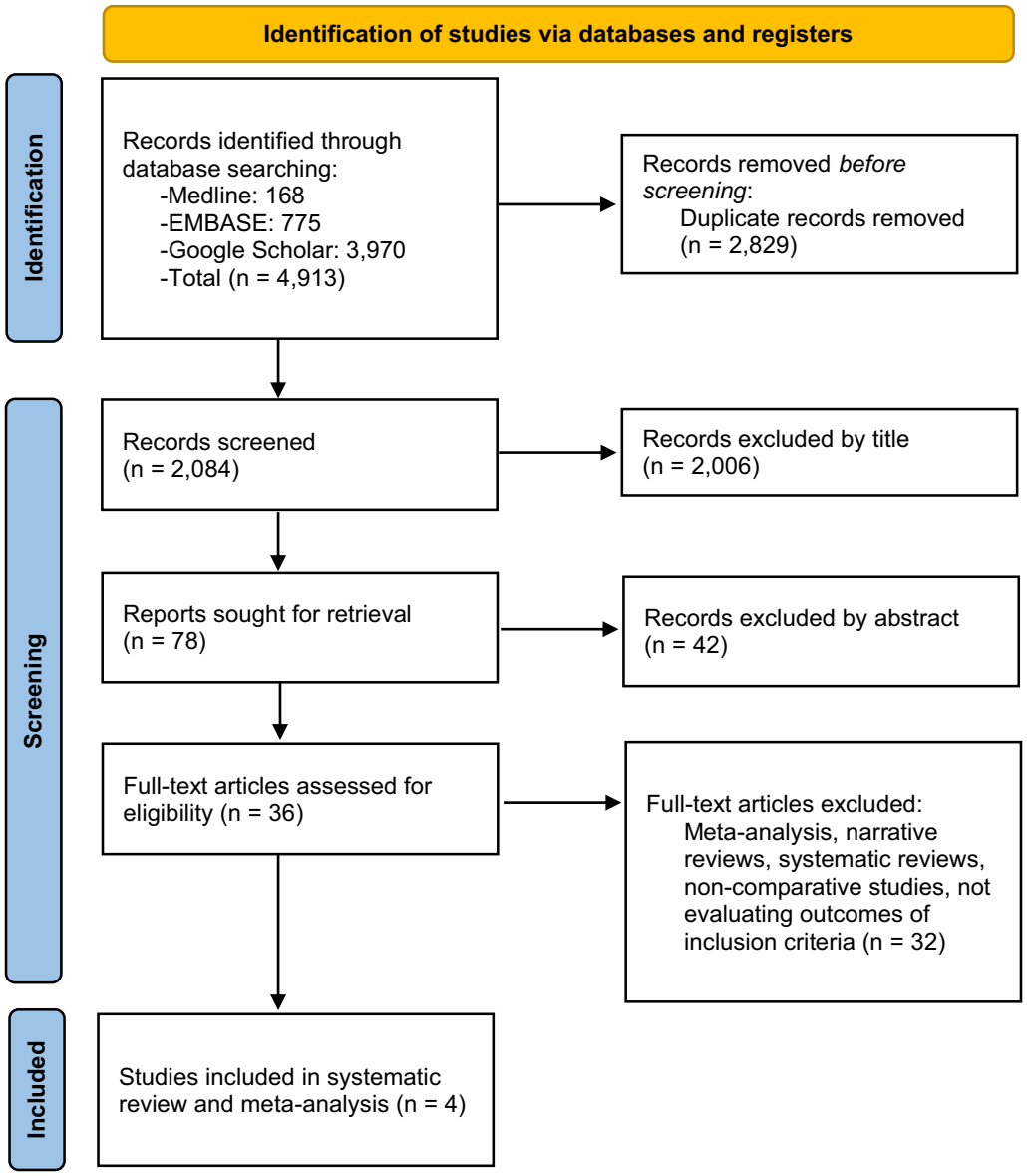
Alanine Aminotransferase (ALT in U/l)

Three studies [16, 18, 19], including a total of 160 patients, reported the effect of ESG on the liver enzymes using ALT. One-year post-ESG, there was a decrease of 6.32 U/l in the ALT (95% CI − 9.52 to − 3.11; $I^2 = 8\%$; $P < 0.01$) (Fig. 4).

Total Weight Loss (TWL in %)

Four studies [16–19], including a total of 175 patients, reported the %TWL. One-year post-ESG, the mean 17.28%TWL (95% CI − 18.24 to − 16.31; $I^2 = 41\%$; $P < 0.01$) was reported (Fig. 5).

Table 1 PRISMA diagram flow



Body Mass Index (BMI in kg/m.^{2})

Three studies [16, 17, 19], including a total of 57 patients, evaluated the effects of ESG on weight loss using BMI. One-year post-ESG, there was a BMI reduction of 6.31 kg/m^2 (95% CI − 8.11 to − 4.52; $I^2 = 0\%$; $P < 0.01$) (Fig. 6).

Excess Weight Loss (EWL in %)

Four studies [16–19], including a total of 175 patients, reported the effect of ESG on EWL. One-year post-ESG, the mean %EWL was 47.97% (95% CI − 49.10 to − 46.84; $I^2 = 0\%$; $P < 0.01$) (Fig. 7).

Glycated Hemoglobin A1c (HbA1c in %)

Four studies [16–19], including a total of 175 patients, reported the effect of ESG on T2DM using HbA1c. High heterogeneity was identified, and the random effect model was used. One-year post-ESG, there was a HbA1c reduction of 0.51% (95% CI − 0.90 to − 0.12; $I^2 = 70\%$; $P = 0.01$) (Fig. 8).

Discussion

This is the first systematic review with meta-analysis to assess the role of ESG on NAFLD. The results demonstrate that ESG is associated with significant improvement in

Table 2 Characteristics of included studies in the meta-analysis

Study	Country	Study design	Number of patients	Mean age (years)	Female (%)	Baseline BMI (kg/m^2)	Follow-up (months)	Outcomes analyzed
Carr P 2022	Australia	Comparative observational (versus LSG)	16	41 ± 10	81	35 ± 5	12	HSI, ALT, BMI, %TWL, %EWL, HbA1c
Espinet-Coll E 2019	Spain	Comparative observational (versus IGB)	15	47 ± 16	73	40 ± 6.8	12	NFS, HSI, BMI, %TWL, %EWL, HbA1c
Hajifathalian K 2021	USA	Non-comparative observational	118	46 ± 13	68	40 ± 7	24	NFS, HSI, ALT, %TWL, %EWL, HbA1c
Jagtap N 2021	India	Non-comparative observational	26	41 ± 9	61	36 ± 5	12	NFS, HSI, ALT, BMI, %TWL, %EWL, HbA1c

Abbreviation index: *LSG* laparoscopic sleeve gastrectomy; *IGB* intragastric balloon, *NFS* non-alcoholic fatty liver disease fibrosis score, *HSI* hepatic steatosis index, *ALT* aspartate aminotransferase, *BMI* body mass index, *%TWL* percentage total weight loss; *%EWL* percentage excess weight loss; *HbA1c* glycated hemoglobin A1c

hepatic steatosis, liver fibrosis, anthropometric parameters, and T2DM in patients suffering from obesity and NAFLD after at least 1 year of follow-up.

Due to the high prevalence and increasing incidence of NAFLD globally, there are standard diagnostic methods to identify patients at risk of developing the disease and its complications. Liver biopsy remains the gold standard for the diagnosis of NAFLD, defined by the presence of 5% hepatocytic involvement [20]. However, this method is associated with a non-negligible rate of adverse events, such as pain, infection, bleeding, and pneumothorax. Thus, non-invasive techniques (NIT) were developed, using serum biomarkers and imaging based on ultrasound or magnetic resonance elastography analysis. These methods are more feasible for widespread adoption, even though, the NITs are usually not sufficient for the definitive diagnosis of NAFLD [21, 22]. Despite the degree of hepatic fibrosis being the most important factor in defining the risks associated with NAFLD progression, there are currently no data in the literature comparing histopathological parameters prior to and after ESG. Among the non-invasive approaches, the NFS and fibrosis-4 (FIB-4) are the most reliable for ruling out the advanced stage of NAFLD. Nonetheless, the NFS was the only score available to meta-analyze. This score is composed of age, BMI, presence or absence of hyperglycemia, platelet count, albumin level, and the ratio of AST to ALT. The NFS significantly improved post-ESG, decreasing 0.5 points in 1-year follow-up. Despite the statistical analysis demonstrating improvement in NFS one-year post-ESG, all included studies analyzing this outcome persisted in the initial category: two studies [18, 19] maintained average levels as indeterminate and the other [17] as F0–F2. In patients with NFS category F3–F4, the impact of ESG has yet not been evaluated. Consequently, more data are needed to confirm if ESG is effective to interrupt the evolution of liver cirrhosis and the development of HCC.

HSI is also a NIT, which evaluates earlier stages of NAFLD, being a practical and inexpensive method for screening steatosis with reasonable accuracy [23]. HSI is calculated using ALT/AST ratio, BMI, and other clinical data. HSI values above 36.0 diagnoses NAFLD with a sensitivity of 93.1% and specificity of 92.4% [21]. Although ultrasound elastography has comparable accuracy to HSI in determining NAFLD, only one study [17] evaluated it, reporting a significant impact of ESG on NAFLD, reducing steatohepatitis degree and subcutaneous fat thickness. Although ESG reduced HSI values with statistical significance by a mean of 4.85, post-ESG values maintained above 36 in all included studies [16–19]. Thus, the effectiveness of ESG in NAFLD remains unclear.

Multivariate analysis indicated that high serum ALT, high BMI, and T2DM were independent risk factors for NAFLD

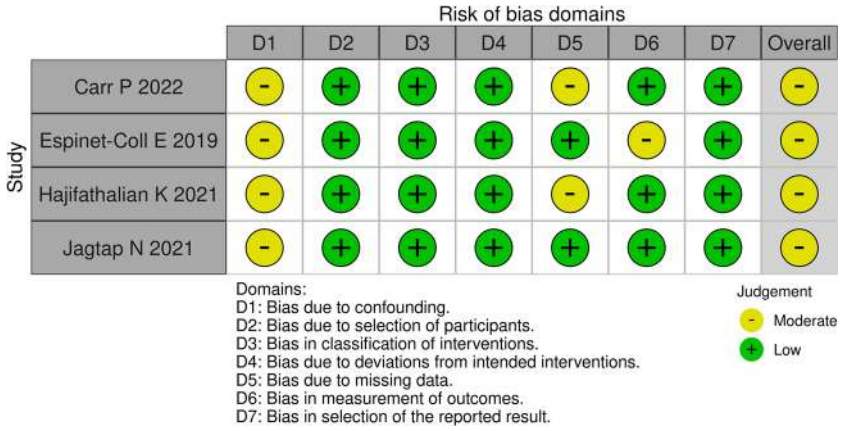


Fig. 1 Cochrane Risk of Bias in Non-randomized Studies of Interventions (ROBINS-I)

[6]. In this meta-analysis, patients' ALT levels decreased by 6.32 U/l 1 year after ESG. A large retrospective multicentric study [24] including 92 patients reported similar results, with a reduction of 8.62 U/l at 3-month follow-up. Despite the reduction in ALT parameters reported in this meta-analysis, of the three studies evaluating this outcome, two [16, 18] reported normal ALT values in pre- and post-procedure analysis, and one [19] maintained elevated values before and after ESG.

Currently, weight loss achieved by LI remains the primary treatment of NAFLD. The American Society for Metabolic and Bariatric Surgery considers the %TWL fundamental to determine the metabolic results [25]. Although 5%TWL has been shown to improve steatosis, a threshold of 10%

Table 3 Quality of evidence assessed by GRADE

Outcomes	No. of participants (studies) follow-up	Certainty of the evidence (GRADE)	Anticipated absolute effects Risk difference with ESG in NAFLD patients
HSI	175 (4 observational studies)	⨁⨁⨁◯ Moderate[a]	MD **4.85 lower** (6.02 lower to 3.67 lower)
NFS	159 (3 observational studies)	⨁⨁⨁◯ Moderate[a]	MD **0.5 lower** (0.8 lower to 0.19 lower)
ALT	160 (3 observational studies)	⨁⨁⨁◯ Moderate[a]	MD **6.32 lower** (9.52 lower to 3.11 lower)
HbA1c	175 (4 observational studies)	⨁⨁◯◯ Low[a,b]	MD **0.51 lower** (0.9 lower to 0.12 lower)
Body Mass Index	57 (3 observational studies)	⨁⨁⨁◯ Moderate[a]	MD **6.31 lower** (8.11 lower to 4.52 lower)
Total Weight Loss (%)	175 (4 observational studies)	⨁⨁⨁◯ Moderate[a]	MD **17.28 lower** (18.24 lower to 16.31 lower)
Excess Body Loss (%)	175 (4 observational studies)	⨁⨁⨁◯ Moderate[a]	MD **47.97 lower** (49.1 lower to 46.84 lower)

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI)

GRADE Working Group grades of evidence

High certainty: we are very confident that the true effect lies close to that of the estimate of the effect

Moderate certainty: we are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low certainty: our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect

Very low certainty: we have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect

CI confidence interval; *MD* mean difference

[a]Moderate risk of Bias through the ROBINS-I

[b]Heterogeneity > 50% and < 75%

is required to improve the histologic features of fibrosis in NAFLD [22]. Musso G et al. [3] meta-analyzed and showed that exclusive LI failed to achieve 7% TWL in more than half of the patients, even after pharmacological therapies, implying no difference in hepatic fibrosis as a predictor for the progression of advanced liver disease. Our meta-analysis demonstrated that ESG induced a mean of 17% TWL, following the results of a recent meta-analysis [10], which included 2170 patients from 11 studies showing a pooled mean %TWL at 6, 12, and 18 months post-ESG of 15.32%, 17.33%, and 16.8%, respectively. This meta-analysis showed that ESG also reduced both BMI and %EWL significantly, similar to a multicenter randomized trial [26], which showed that ESG improved the anthropometric parameters, including a higher %EWL than the LI group in 12 months (49.2% versus 3.2%, $p < 0.01$, respectively.

T2DM is an independent risk factor for NAFLD, and hepatic steatosis resolution can prevent the hyperglycemia onset [27]. The association between those metabolic diseases can be characterized by IR, abnormal triglycerides, and fatty liver parameters, leading to inflammatory response and beta-cell pancreatic dysfunction. Our study demonstrated a reduction with a statistical significance of 0.51% in HbA1c. Although there was a reduction in HbA1c in all studies [16–19], only one study [19] had a baseline HbA1c higher than 6.5% before and after the procedure. These findings suggest that the mechanism of how ESG improves NAFLD may be similar to other weight loss therapies through the IR pathway [10], as described by Espinet Coll et al. [17], who demonstrated a significant improvement in HOMA-IR. Sharaiha et al. [28] evaluated 91 patients and showed that ESG is an effective endoscopic weight loss intervention with sustained %TWL up to 24 months and reduced HbA1c. Both T2DM and NAFLD are chronic metabolic diseases that are usually asymptomatic, preceding cardiovascular, renal, and oncologic complications [27].

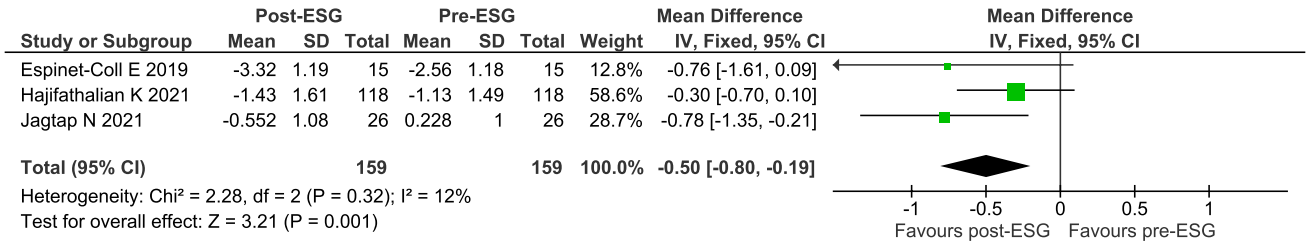


Fig. 2 Non-alcoholic fatty liver disease fibrosis score (NFS) 1-year post-ESG

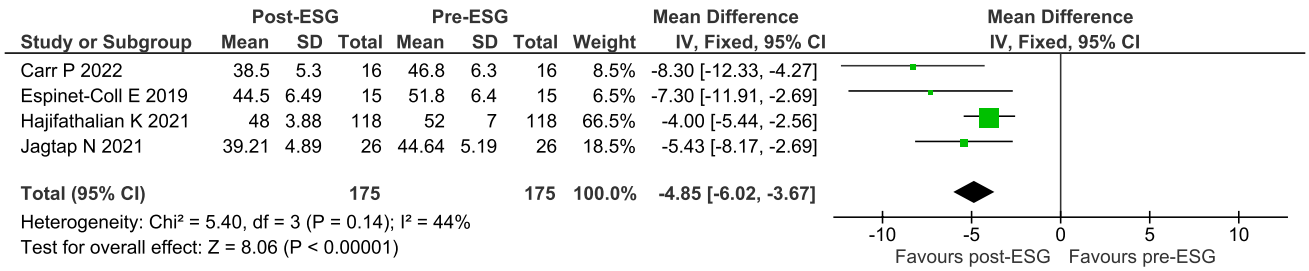


Fig. 3 Hepatic steatosis index (HSI) 1-year post-ESG

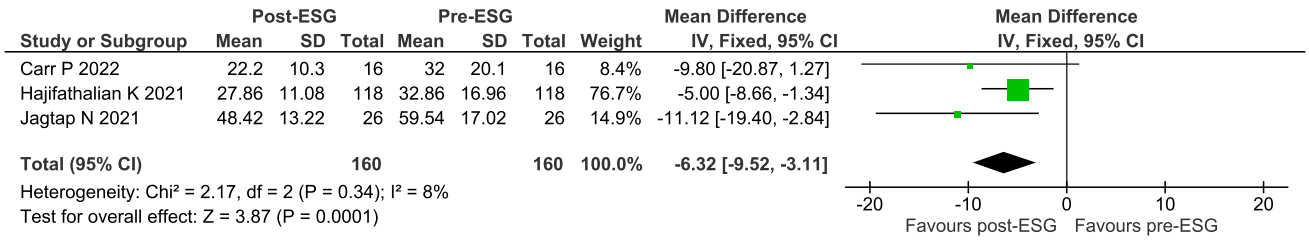


Fig. 4 Alanine aminotransferase (ALT in U/l) 1-year post-ESG

In the literature, ESG can improve T2DM parameters by mechanisms mainly related to reducing IR, delayed gastric emptying, and inducing early satiety, followed by gut and metabolic hormone changes with a significant reduction in leptin levels [29].

Although it is not yet approved by IFSO, ESG is FDA approved procedure, and its effectiveness, at least in short-term follow-up has been proved from several studies, including RCTs [26], prospective and retrospective multicenter studies, and several meta-analyses [8–10]. Furthermore, the ESG safety profile is also recognized by different renowned societies [30, 31]. Despite its effectiveness and safety, this procedure cannot be compared to surgical outcomes, which is still the gold-standard procedure for obesity and its comorbidities, including NASH. Nevertheless, these procedures should not be compared, and the choice between them to improve a patient's quality of life requires individual evaluation.

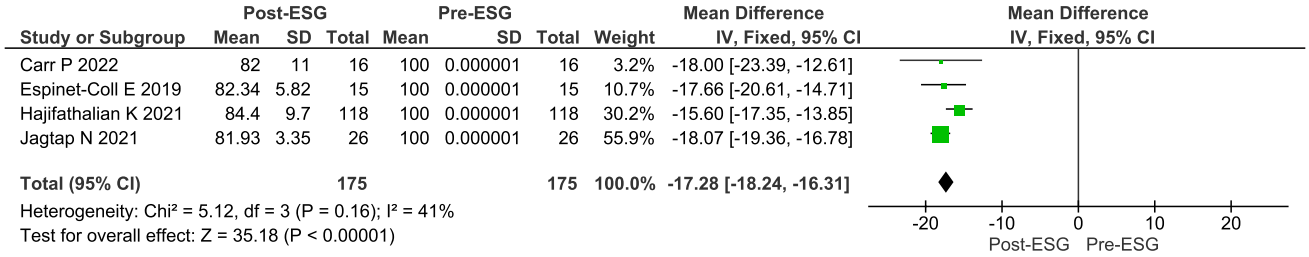


Fig. 5 Total weight loss (%TWL) 1-year post-ESG

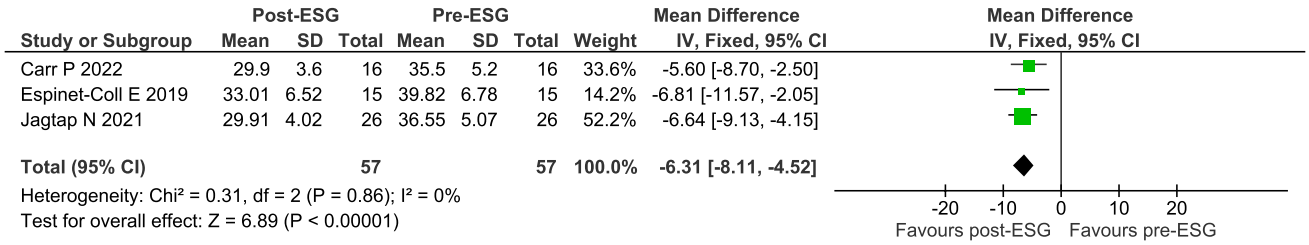


Fig. 6 Body mass index (BMI in kg/m^2) 1-year post-ESG

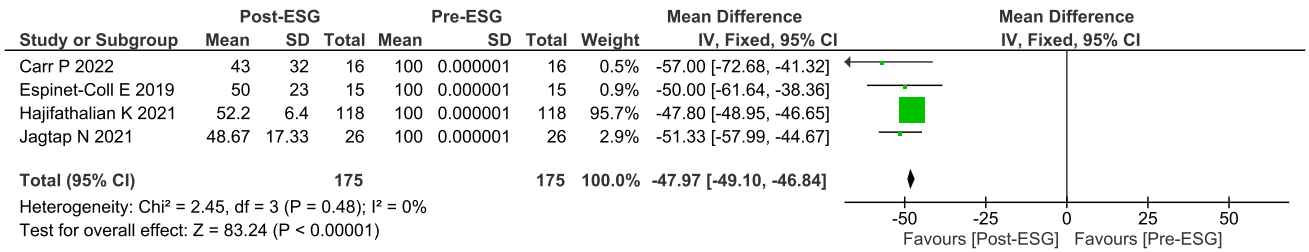


Fig. 7 Excess weight loss (%EWL) 1-year post-ESG

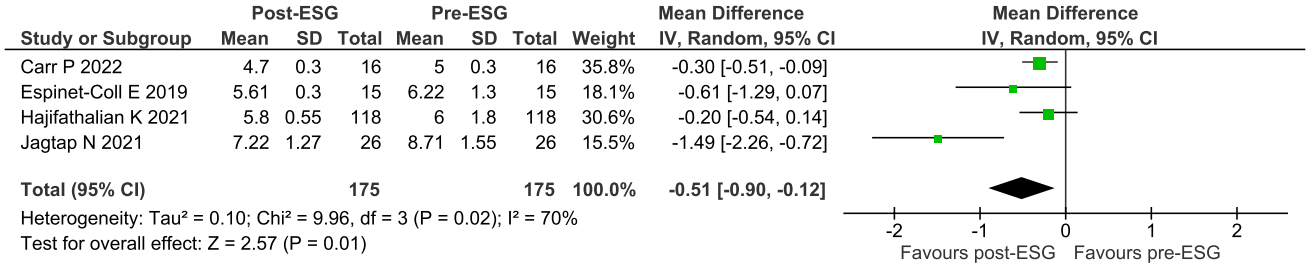


Fig. 8 Glycated hemoglobin A1c (%HbA1c) 1-year post-ESG

Despite being the first meta-analysis evaluating the role of ESG for NAFLD, this study has several limitations. First, there is a lack of high-quality studies evaluating ESG for NAFLD. Second, the available data present heterogeneous inclusion criteria, and most studies include patients with a low degree (F0–F2) of NAFLD. Third, there are no studies evaluating patients with NAFLD diagnosed by liver biopsy, which is the gold-standard method. Although the American Association for the Study of Liver Diseases states that a liver biopsy may not be essential for diagnosing NAFLD, we recognize that NIT is still substandard to replace histological analysis [32]. Last, most studies have a retrospective design, which can lead to confounding bias. Furthermore, the high percentage of missing data lost to follow-up leads to an overestimation of the treatment effect. The longest available follow-up period was 2 years. Therefore, long-term effects could not be assessed. RCT with well-defined inclusion criteria (i.e., NAFLD diagnosed by liver biopsy) and long-term follow-up are warranted to confirm the benefits of ESG for this challenging condition.

In summary, our study demonstrates that ESG is a promising approach for patients suffering from obesity associated with NAFLD, promoting satisfactory weight loss, and improving liver parameters. Thus, it has the potential to prevent the progression of liver fibrosis, cirrhosis, and HCC. Moreover, it is worth remembering that LI and follow-up with a multidisciplinary team are required for successful clinical outcomes after any type of weight loss procedure.

Conclusion

This systematic review and meta-analysis demonstrate the benefits of ESG in improving liver steatosis parameters, providing satisfactory weight loss, and reducing HbA1c levels after at least 12 months of follow-up. Therefore, ESG appears to be a reasonable treatment option for patients suffering from obesity and NAFLD.

Author Contribution BCMN: acquisition of data, analysis, interpretation of data, drafting the article, revising the article, final approval; DTHM: interpretation of data, drafting the article, revising the article, final approval; ASTK: acquisition of data, analysis, drafting the article, final approval; GHPO: analysis and interpretation of data, revising the article, final approval; BSH: drafting the article, revising the article, final approval; IBR: interpretation of data, revising the article, final approval, ILCG: acquisition of data, analysis, drafting the article, final approval; CPMO: interpretation of data, critical revision, final approval; SM: revising the article, language adequacy, final approval; WMB: analysis and interpretation of data, critical revision, final approval; EGHM: conception and design of the study, critical revision, final approval.

Declarations

Ethics Approval The study was approved by the Research Ethics Committee of the University of São Paulo School of Medicine Hospital das Clínicas.

Conflict of Interest Dr. Diogo Turiani Hourneaux De Moura: BariaTek Medical—Advisory Board Member (Consulting fees). This was not relevant to this study. Dr. Eduardo Guimaraes Hourneaux De Moura: Olympus—Consultant (Consulting fees) and Boston Scientific—Consultant (Consulting fees). These were not relevant to this study. The other authors declare no potential conflict of interest.

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