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INTEGRATED THERAPY WITH GLP-1 RECEPTOR AGONISTS AND NUTRITIONAL INTERVENTIONS IN THE TREATMENT OF OBESITY IN PATIENTS WITH TYPE 2 DIABETES

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Summary

Obesity and type 2 diabetes represent a major public health challenge, and their strong interrelationship requires integrated therapeutic approaches. GLP-1 receptor agonists have, in recent years, taken a central role in the pharmacotherapy of diabetes and obesity due to their effects on appetite regulation, body weight reduction, and glycaemic control. At the same time, wellstructured medical nutrition therapy remains the foundation of non-pharmacological weightmanagement strategies. However, the combination of GLP-1 receptor agonists with individualized dietary interventions is still insufficiently explored in real-world clinical settings. The aim of this study was to investigate the effects of combined therapy with GLP-1 RA and nutritional interventions in patients with type 2 diabetes and obesity, and to compare the findings with those reported in the SUSTAIN and LEADER clinical trial programs**.** Parameters monitored over a six-month period included body weight, body mass index, waist circumference, HbA1c, blood pressure, lipid profile, renal parameters, and liver enzymes. The results show that combined therapy leads to statistically and clinically significant improvements in all major metabolic outcomes. Body weight decreased by −8.60 kg (−7.82%), BMI by −3.14 kg/m², waist circumference by −4.97 cm, and HbA1c by −1.99%. Additionally, moderate reductions in blood pressure, total cholesterol, and ALT levels were observed. The findings indicate that the combination of GLP-1 RA and well-guided nutritional therapy produces stronger effects than those reported in the SUSTAIN and LEADER programs. This study confirms that an integrated approach, combining pharmacological therapy with individualized nutritional support, represents an optimal model for managing obesity in patients with type 2 diabetes.

Keywords: GLP-1 RA, semaglutide, liraglutide, obesity, type 2 diabetes, medical nutrition therapy

Introduction

Obesity and type 2 diabetes mellitus (T2DM) represent two of the most prevalent and clinically significant metabolic disorders worldwide. Their close pathophysiological relationship is primarily driven by insulin resistance, systemic inflammation, and impaired regulation of energy balance. Obesity increases the risk of developing type 2 diabetes by three to five times, while the presence of diabetes further complicates weight reduction and the maintenance of achieved weight loss. Glucagon-like peptide-1 receptor agonists (GLP-1 RA) have in recent years become cornerstone therapies for the management of both diabetes and obesity. Their mechanisms of action include delayed gastric emptying, appetite suppression, enhanced insulin secretion, and reduced glucagon release. Clinical studies, including the SUSTAIN program, have demonstrated that GLP-1 RAs significantly reduce HbA1c and lead to moderate reductions in body weight in patients with T2DM. Despite these advances, dietary intervention remains a crucial component of obesity management. Caloric restriction, increased intake of dietary fiber, and reduction of refined carbohydrates have been shown to contribute to weight loss, reductions in abdominal obesity, and improved glycemic control. However, long-term patient adherence remains a major challenge.

Because GLP-1 RAs facilitate dietary adherence by reducing hunger and preference for energy-dense foods, it is hypothesized that combining pharmacotherapy with personalized nutrition may yield superior outcomes compared to either intervention alone. The aim of this study was to evaluate the metabolic effects of combined GLP-1 RA therapy and structured dietary intervention in patients with type 2 diabetes and obesity and to compare these findings with results from the SUSTAIN (Semaglutide Unabated Sustainability in Treatment of Type 2 Diabetes) and LEADER (Liraglutide Effect and Action in Diabetes: Evaluation of Cardiovascular Outcome Results) clinical programs.

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Mathreials and methods

Study design

The study was conducted at the Public Health Institution "Dom zdravlja Živinice," within the Consultative-Specialist Service, and was designed as a six-month prospective clinical investigation. This design enabled follow-up of changes in metabolic and anthropometric parameters within the same group of participants across predefined time intervals. The prospective approach ensured systematic and chronologically consistent data collection, reducing the risk of bias typical of retrospective studies. The obtained results were compared with findings from relevant international clinical trials—primarily SUSTAIN and LEADER—to assess the alignment of local outcomes with established evidence on the efficacy and safety of GLP-1 receptor agonists. Throughout the study, participants attended regular follow-up visits according to a predetermined schedule, which enhanced the consistency and reliability of the collected data.

Participants

The study included 30 patients with confirmed type 2 diabetes and obesity, with a body mass index (BMI) ≥ 35 kg/m². All participants were adults, clinically stable, and under regular supervision of a diabetologist. Inclusion criteria were: age ≥ 18 years; type 2 diabetes mellitus of at least one year in duration; stable antidiabetic therapy for at least three months prior to enrollment; BMI ≥ 35 kg/m², and ability to comply with the study protocol. Exclusion criteria were:acute or chronic liver or kidney disease; active malignancy; type 1 diabetes; pregnancy and breastfeeding.

Interventions

*Pharmacological intervention***.** All participants received treatment with GLP-1 receptor agonists—liraglutide or semaglutide—in accordance with current guidelines from the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) for the management of T2DM and obesity, ensuring ethical justification and avoiding any experimental or off-label approaches. Liraglutide was administered subcutaneously once daily, while semaglutide was administered subcutaneously once weekly.
Dosing was individualized based on tolerance and therapeutic response. Throughout the study, side effects, adherence, and metabolic response were systematically monitored.

Nutritional intervention. In addition to pharmacotherapy, all participants followed a structured dietary plan consistent with modern nutritional recommendations for individuals with T2DM and obesity. The intervention included: a daily caloric deficit of 500–750 kcal; increased intake of dietary fiber (whole grains, vegetables, legumes); reduced intake of refined carbohydrates, saturated fats, and industrially processed foods.

Participants attended monthly sessions with a nutritionist to monitor adherence, support motivation, and adjust dietary plans to individual needs. The integration of pharmacological and nutritional therapy enabled a synergistic effect, consistent with current approaches to managing T2DM and obesity.

Statistical analysis

Descriptive statistics were used to present the baseline characteristics of the sample. To compare data across the three time points in baseline, after 3 months, and after 6 months a one-way repeated-measures analysis of variance (ANOVA) was applied, followed by Bonferroni post-hoc testing to identify statistically significant differences between intervals. A p-value < 0.05 was considered statistically significant.

Results

Table 1 presents the basic characteristics of the participants, including age and diabetes duration. The mean age of the study sample was 59.9 ± 6.5 years, while the average duration of diabetes was 8.73 ± 5.65 years. These data indicate a relatively homogeneous baseline sample structure, which is essential for valid interpretation of changes observed following the intervention (Sorli et al., 2017; Pratley et al., 2018). Sample homogeneity reduces the influence of potential confounding factors and allows more reliable conclusions regarding the effects of the treatment.

Table 1. Baseline characteristics of participants

Variable	Value
Number of participants	30
Age (years)	59.9 ± 6.5
Duration of T2DM (years)	8.73 ± 5.65

Table 2 shows the trajectory of body weight reduction throughout the study period. A clear progressive decrease in body weight was observed, with a statistically significant reduction already after three months of intervention (−5.04 kg; $p < 0.001$). This trend continued in the following period, resulting in a total mean weight loss of 8.60 kg after six months ($p < 0.001$). These findings indicate a stable and clinically meaningful improvement in weight control.

Table 2. Changes in body weight (BW)

Time period	BW (kg)	Change (kg)	p
Baseline	110.00	—	—
3 months	104.96	−5.04	<0.001
6 months	101.40	−8.60	<0.001

Table 3 illustrates the changes in BMI during the follow-up period. A statistically significant reduction in BMI was observed after three months (−1.78 kg/m²; $p < 0.001$), which further deepened by the sixth month, reaching a total reduction of −3.14 kg/m² ($p < 0.001$). These findings reflect a continuous and clinically relevant reduction in adipose tissue mass, consistent with the expected physiological effects of the intervention. The results confirm the effectiveness of the treatment in improving anthropometric parameters over time.

Table 3. Changes in Body Mass Index (BMI)

Time period	BMI (kg/m²)	Change (kg/m²)	P
Baseline	40.95	—	—
3 months	39.17	−1.78	<0.001
6 months	37.81	−3.14	<0.001

Changes in waist circumference presented in Table 4 show a significant decrease at both time points—after three and after six months (−3.04 / −4.97 cm), reflecting a reduction in visceral adipose tissue, one of the key predictors of cardiometabolic risk.

Table 4. Changes in waist circumference (WC)

Time period	WC (cm)	Change (cm)	P
Baseline	121.27	—	—
3 months	118.23	−3.04	<0.001
6 months	116.30	−4.97	<0.001

The reduction in HbA1c presented in Table 5 amounting to −1.99% after six months of therapy, represents a remarkably strong therapeutic response. A statistically significant decrease in HbA1c was observed as early as the three-month follow-up, with further improvement at six months.

Table 5. Changes in HbA1c

Time period	HbA1c (%)	Change (%)	P
Baseline	8.88	—	—
3 months	7.07	−1.81	<0.001
6 months	6.89	−1.99	<0.001

Table 6 shows the reduction in systolic and diastolic blood pressure after six months of therapy, reaching statistical significance ($p = 0.02$).

Table 6. Changes in blood pressure after 6 months of therapy

Parameter	Blood pressure (mmHg)	p
Systolic BP	−6.03 mmHg	0.02
Diastolic BP	−3.28 mmHg	0.02

Table 7 demonstrates a reduction in total cholesterol of 0.71 mmol/L, which is statistically significant ($p = 0.01$). Although triglycerides decreased by 0.54 mmol/L, this change did not reach statistical significance ($p = 0.17$).

Table 7. Changes in lipid profile

Parameter	Lipids (mmol/L)	p
Total cholesterol	−0.71 mmol/L	0.01
Triglycerides	−0.54 mmol/L	0.17

The reduction in liver enzymes ALT and AST is shown in Table 8. A significant reduction in ALT (−6.60 U/L) was observed ($p = 0.01$), while the decrease in AST was minimal and statistically non-significant ($p = 0.88$).

Table 8. Liver function parameters

Parameter	Status	P
ALT (Alanine aminotransferase)	−6.60 U/L	0.01
AST (Aspartate aminotransferase)	stable	0.88

Renal function parameters presented in Table 9 remained stable throughout the entire follow-up period. No statistically significant changes were observed in urea or creatinine levels ($p = 0.17$), indicating that the applied intervention had no adverse effects on kidney function. These results further support the safety profile of the treatment in relation to monitored renal biomarkers.

Table 9. Renal function parameters

Parameter	Status	P
Urea	stable	0.17
Creatinine	stable	0.17

Table 10 presents the results of repeated-measures ANOVA for three key anthropometric variables: body weight (BW), waist circumference (WC), and BMI at baseline, 3 months, and 6 months. Body weight showed a continuous and statistically significant decline, with a very strong effect size ($\eta^2 = 0.71$). Waist circumference also decreased progressively, reflecting reductions in abdominal adiposity, with an equally strong treatment effect ($\eta^2 = 0.71$). BMI demonstrated a consistent downward trend across all time points, accompanied by a large effect size ($\eta^2 = 0.67$), further confirming the intervention's effectiveness in improving body composition.

Table 10. Analysis of variance with repeated measurements of the variables body weight, waist circumference and body mass index

Variables	Time period	N	M	SD	Wilks lambda	F	p	Partial eta squared
BW	Baseline	30	110.00	20.43	—	—	—	—
	3 months	30	104.96	20.30	0.29	34.71	0.00	0.71
	6 months	30	101.40	20.18	—	—	—	—
WC	Baseline	30	121.17	12.61	—	—	—	—
	3 months	30	118.23	12.42	0.29	34.16	0.00	0.71
	6 months	30	116.30	12.14	—	—	—	—
BMI	Baseline	30	40.95	4.20	—	—	—	—
	3 months	30	39.17	4.22	0.33	28.04	0.00	0.67
	6 months	30	37.81	4.23	—	—	—	—

Highly statistically significant differences were observed across all three variables over time ($p < 0.001$), with Wilks' lambda values ranging from 0.29 to 0.33, indicating a strong multivariate effect of time—i.e., of the therapeutic intervention. The partial eta-squared coefficients ($\eta p^2 = 0.67–0.71$) indicate a very large effect size, meaning that GLP-1 agonists combined with dietary intervention explained more than 67% of the variance in BW, WC, and BMI.

Discussion

The results of this study show that the combination of GLP-1 receptor agonists and medical nutrition therapy leads to markedly better metabolic and anthropometric outcomes compared with standard therapy in patients with type 2 diabetes and obesity. To better understand the significance of these findings, they were systematically compared with the results of two of the most relevant groups of clinical trials: the SUSTAIN program, which evaluated semaglutide in various populations of patients with T2DM, and the LEADER trial, the key cardiovascular outcome trial assessing the efficacy and safety of liraglutide in individuals with type 2 diabetes.

Comparison with SUSTAIN 1–7 shows that the effects of our intervention on body weight reduction (−7.82%) and HbA1c improvement (−1.99%) are stronger than the typical values reported in those trials (3.7–6.9% weight loss; HbA1c reduction of 1.2 to 1.8%). Similarly, comparison with the LEADER trial indicates that other metabolic markers, such as blood pressure, abdominal obesity, and total cholesterol, also improved to a greater extent in our study. This difference most likely arises from combining pharmacotherapy with a structured dietary intervention, as well as from the fact that our participants were treated with more potent GLP-1 receptor agonists (semaglutide), whereas LEADER included liraglutide only.

Taken together, both sources of evidence confirm a consistent direction of effect of GLP-1 receptor agonists, while at the same time highlighting that an integrated therapeutic approach, such as the one applied in our study, can lead to faster and more pronounced improvements. Below, we provide a detailed overview of the key differences in outcomes between our study and the SUSTAIN and LEADER trials.

Our study demonstrated that the combination of GLP-1 RAs and medical nutrition therapy yields superior clinical effects compared with standard therapy. The results exceeded those of the SUSTAIN trials, in which weight loss ranged from 3.7 to 6.9%, whereas in our study it reached 7.82%.

The outcomes of our research surpass the typical effects of GLP-1 RAs reported in the SUSTAIN trials, where reductions in body weight were less pronounced (3.5–6.5 kg) in individuals with T2DM (Aroda et al., 2017; Sorli et al., 2017), suggesting synergy with the dietary intervention. The reduction in BMI (−3.14 kg/m²) indicates a statistically significant loss of adipose tissue. A similar but less pronounced effect of GLP-1 RAs on BMI was reported in SUSTAIN 2 and SUSTAIN 3 (Aroda et al., 2017; Ahmann et al., 2018), which further underscores the importance of integrated nutritional support.

The significant reduction in waist circumference at both time points in our study, after three and six months (−3.04 / −4.97 cm), reflects a decrease in visceral adipose tissue, one of the key predictors of cardiometabolic risk. This magnitude of change is comparable to the MRI findings from SUSTAIN 7, which showed a 15–20% reduction in visceral fat (Pratley et al., 2018).

The reduction in HbA1c of −1.99% after six months of therapy represents a remarkably strong therapeutic response. A statistically significant reduction in HbA1c in our study was achieved as early as three months, with a further decline observed at six months, exceeding the results of the SUSTAIN program (−1.2 to −1.8%), including SUSTAIN 6 (Marso et al., 2016). Possible explanations include higher baseline BMI, better adherence, and structured dietary support.

The decreases in systolic (−6.03 mmHg) and diastolic blood pressure (−3.28 mmHg) in patients treated with GLP-1 RAs in our study are in line with previous findings indicating that GLP-1 RAs exert beneficial effects on hemodynamic parameters, primarily via weight reduction and improved vascular function (Marso et al., 2016; Wilding et al., 2021).

The reduction in total cholesterol and triglycerides indicates a favourable effect of therapy on the lipid profile, although the decrease in triglycerides was numerically present but did not reach statistical significance. These results are consistent with findings from SUSTAIN 3 and SUSTAIN 7, which report modest but consistent improvements in lipid parameters (Aroda et al., 2017; Pratley et al., 2018).

The significant reduction in ALT values in our study (−6.60 U/L) suggests regression of steatohepatitis and improvement in liver functional status, which is consistent with earlier studies showing a hepatoprotective effect of GLP-1 RAs (Madsbad, 2016; Nauck & Meier, 2019). Stable AST values indicate the absence of hepatotoxicity.

The stability of urea and creatinine confirms the favourable renal safety profile of GLP-1 RA therapy. These findings are fully consistent with long-term safety data for GLP-1 RAs reported in SUSTAIN 6 and other cardiovascular outcome trials (Marso et al., 2016; Nauck & Meier, 2019). The beneficial effects on blood pressure, lipids, and liver enzymes confirm the systemic benefits of the therapy. Study limitations include the small sample size and non-randomized design, but the results strongly support the use of integrated treatment.

Table 11. Comparison of results from our study and the SUSTAIN clinical program

Outcome	Our study (liraglutide/semaglutide + diet, 6 months)	SUSTAIN 1–7 (semaglutide in T2DM)	Reference
Body weight (kg)	−8.60 (−7.82%)	−3.5 to −6.5	Sorli et al., 2017; Aroda et al., 2017
HbA1c (%)	−1.99	−1.2 to −1.8%	Marso et al., 2016; Davies et al., 2021
Waist circumference (cm)	−4.97	Reduction in visceral fat 15–20%	Pratley et al., 2018
Systolic blood pressure (mmHg)	−6.03	−2 to −5	Marso et al., 2016
Diastolic blood pressure (mmHg)	−3.28	−1 to −2	Marso et al., 2016
Total cholesterol (mmol/L)	−0.71	Moderate reduction	Aroda et al., 2017
ALT (U/L)	−6.60	−4 to −7 U/L	Aroda et al., 2017
Renal function	Stable	Stable	Nauck & Meier, 2019

The LEADER trial is a large, randomized, placebo-controlled cardiovascular outcome study (CVOT) in patients with type 2 diabetes and high cardiovascular risk, published in 2016. It demonstrated that liraglutide reduces the risk of cardiovascular events in patients with type 2 diabetes and increased cardiovascular risk.

Comparison of the results of our six-month intervention (combination of liraglutide/semaglutide and targeted diet) with the outcomes of the LEADER trial, in which liraglutide alone was evaluated in individuals with type 2 diabetes, indicates a consistent direction of effect but considerably more pronounced improvements in almost all parameters in our population (Marso et al., 2016).

The greatest difference is observed in body weight reduction, where our participants achieved an average loss of −8.60 kg (−7.82%), which clearly exceeds the results of LEADER (−2.3 to −3.0 kg). This difference is likely due to two factors: the inclusion of a more potent GLP-1 receptor agonist (semaglutide) and the structured dietary program, which was not present in LEADER. Similarly, the reduction in HbA1c in our study (−1.99%) is almost twice that reported in

LEADER, indicating a stronger glycaemic response with the integrated therapeutic approach.

Blood pressure parameters (systolic and diastolic) also show greater improvements in our study, which can be partly explained by the greater weight loss, improved metabolic status, and potential additional effects of semaglutide. The reduction in waist circumference (−4.97 cm) further confirms substantial visceral fat loss, whereas the LEADER trial reports only moderate, non-quantified reductions.

Regarding the lipid profile, our study shows a moderate reduction in total cholesterol (−0.71 mmol/L), which is more pronounced than the modest changes seen in LEADER (≈0.2–0.3 mmol/L). ALT results are comparable, with both studies confirming the hepatoprotective potential of GLP-1 receptor agonists. Finally, renal function remained stable in both studies, although LEADER additionally points to a slowing of the progression of microvascular damage during long-term follow-up (Marso et al., 2016).

Overall, our study demonstrates stronger metabolic and anthropometric effects compared with LEADER, underscoring the importance of combining GLP-1 receptor agonist pharmacotherapy with targeted dietary interventions, as well as the use of more potent, newer-generation agents.

Table 12. Comparison of results from our study and the LEADER trial

Outcome	Our study (liraglutide/semaglutide + diet, 6 months)	LEADER trial (liraglutide in T2DM)
Body weight (kg)	−8.60 (−7.82%)	−2.3 to −3.0 kg
HbA1c (%)	−1.99%	−1.0 to −1.3%
Waist circumference (cm)	−4.97 cm	Moderate reduction; not quantified
Systolic blood pressure (mmHg)	−6.03 mmHg	−2.3 to −3.0 mmHg
Diastolic blood pressure (mmHg)	−3.28 mmHg	−1.5 to −2.0 mmHg
Total cholesterol (mmol/L)	−0.71 mmol/L	Mild reduction (≈0.2–0.3 mmol/L)
ALT (U/L)	−6.60 U/L	Reduction of 5–7 U/L
Renal function	Stable	Stable / slowed progression of nephropathy

Conclusion

In the study, patients treated with GLP-1 receptor agonists achieved a total body weight reduction of 8.6 kg, or −7.82%, which is superior to results from the SUSTAIN trials, where semaglutide produced an average weight reduction between −3.7% and −6.9%, depending on dose and study population. Similar to the SUSTAIN program, the greatest weight loss occurred during the first three months, followed by continued steady reduction through month six.

The reduction in HbA1c observed in the study (−1.99%) was greater than that reported in the SUSTAIN trials (semaglutide: −1.2 to −1.8%) and the LEADER trial (liraglutide: −1.0 to −1.3%), further highlighting the importance of medical nutrition therapy and the benefits of an integrated treatment approach (pharmacotherapy + diet therapy). As in the SUSTAIN and LEADER programs, the largest improvement in HbA1c occurred within the first 12 weeks, followed by stabilization of glycemic control. The results of the study demonstrated a reduction in waist circumference of −4.97 cm and a total decrease in BMI of −3.14 kg/m². Comparable but smaller changes in anthropometric parameters have been reported in the SUSTAIN program, where GLP-1 receptor agonists are particularly effective in reducing abdominal adiposity—a key determinant of cardiometabolic risk. Alsom the study documented a statistically significant decrease in both systolic and diastolic blood pressure, with a more pronounced effect after six months. These findings are consistent with the LEADER trial. The study results demonstrated reductions in total cholesterol and ALT values, which align with findings from the SUSTAIN studies. Urea and creatinine levels showed no significant changes, consistent with the LEADER trial, in which liraglutide exhibited a neutral or mildly protective effect on renal function.

When comparing the study outcomes with the large-scale global clinical trials SUSTAIN and LEADER, it may be concluded that the use of GLP-1 receptor agonists combined with targeted nutritional intervention represents an effective, safe, and metabolically superior therapeutic strategy for patients with type 2 diabetes and obesity.

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