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Reviews

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NEUROENDOCRINE MODULATION IN ADDICTION: CLINICAL PERSPECTIVES ON GLP-1R AGONISTS

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A – study design, **B** – data collection, **C** – statistical analysis, **D** – interpretation of data, **E** – manuscript preparation, **F** – literature review, **G** – sourcing of funding

ABSTRACT

Background: Substance Use Disorders (SUDs) are a common and serious public health problem. In 2019, the overall death toll attributable to SUDs included 7.7 million deaths related to smoking, 2.4 million due to alcohol use, and approximately 0.5 million resulting from the use of other psychoactive substances. Treatment methods for SUDs typically include psychotherapy, pharmacotherapy, and neuromodulation techniques. Glucagon-like peptide-1 (GLP-1), produced mainly in the small intestine, exerts various peripheral effects. These properties have formed the basis for the use of GLP-1 analogues, initially in the treatment of type II diabetes and more recently in obesity and cardiovascular diseases. GLP-1 also exerts central nervous system effects, which has led to interest in its potential application in the treatment of SUDs.

Aim of the study: The aim of this paper is to review the existing literature on randomized controlled trials (RCTs) evaluating the efficacy of GLP-1 analogues in reducing psychoactive substance use among patients with SUDs.

Materials and methods: The PubMed database was searched using the following terms: "GLP-1" AND ("addiction" OR "substance use"). Only clinical trials with a placebo or active control group were included.

Results: A total of 321 papers were identified, of which 7 met the inclusion criteria. In total, 525 adult participants were included in the analysis, including patients diagnosed with nicotine use disorder (335 participants), alcohol use disorder (175 participants), and cocaine use disorder (13 participants).

Conclusions: Three of the seven reviewed RCTs reported a significant reduction in substance use with GLP-1 receptor (GLP-1R) agonists compared to placebo. Another trial demonstrated similar efficacy only in a specific subgroup of obese participants. The remaining three studies did not report significant effects. Adverse events were common but generally mild and consistent with the known safety profile of GLP-1R agonists. GLP-1R agonists represent a promising new therapeutic approach; however, the limited number of trials and heterogeneity in inclusion criteria and treatment regimens highlight the need for more comprehensive and longer-term research.

KEYWORDS: Glucagon-Like Peptide 1, substance use disorder, dulaglutide, semaglutide

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Background

Substance Use Disorders (SUDs) are a widespread and serious problem, posing a significant challenge for modern medicine and public health. It is estimated that in 2019 alone, the number of premature deaths worldwide related to SUDs amounted to 7.7 million due to smoking, 2.4 million due to alcohol use, and approximately 0.5 million resulting from the use of other drugs [1]. According to data from the State Agency for Prevention of Alcohol-Related Problems (since January 1, 2022 replaced by the National Center for Addiction Prevention), approximately 600,000–800,000 individuals in Poland are addicted to alcohol, while an additional 2 to 3 million people are considered to abuse alcohol without meeting the clinical criteria for addiction [2]. In a survey conducted in 2018–2019 on a random, representative sample of 3,013 Polish adults, 16.1% of respondents reported having used some form of illegal drugs. Besides cannabis (12.1%), the most commonly used substances were new psychoactive substances (so-called "designer drugs") at 3.9% and amphetamine at 2.4%. A total of 5.4% of respondents reported drug use within the past year [3].

Treatment methods for SUDs typically include behavioral interventions, such as cognitive-behavioral therapy (CBT), pharmacotherapy, and neuromodulation techniques. Among the latter are both non-invasive (transcranial) procedures and those requiring surgical intervention (e.g., deep brain stimulation). Medications are available for disorders related to alcohol, nicotine, and opioid use. However, there are still no approved pharmacological treatments for addictions to other substances (e.g., psychostimulants) [1]. This gap in therapeutic options, combined with a growing understanding of the neurobiological mechanisms of addiction, has prompted the search for newer and more effective pharmacological treatments for SUDs [4]. One promising class of compounds under investigation for their potential use in SUD treatment is glucagon-like peptide-1 (GLP-1) analogs.

The history of GLP-1 analogs begins with the discovery of the incretin effect in 1964 [5]. The observation that a greater amount of insulin is secreted after oral rather than intravenous administration of the same amount of glucose led to intensive research on substances responsible for this enhancement, culminating in the discovery of gastric inhibitory polypeptide (GIP) and, in 1986, GLP-1. Since then, numerous compounds acting through the incretin mechanism have been introduced to the market. These include exenatide (approved in 2004 for the treatment of diabetes), sitagliptin (a DPP-IV inhibitor – an enzyme that breaks down GLP-1), liraglutide, semaglutide (with a prolonged half-life allowing once-weekly dosing), and more recently tirzepatide – a dual GLP-1/GIP agonist, among others [6]. Initially developed for diabetes management, GLP-1 analogs have also demonstrated significant benefits in the treatment of obesity and cardiovascular diseases [5].

In addition to their peripheral effects, such as the incretin effect, delayed gastric emptying, and reduced glucagon secretion, GLP-1 also exerts central effects. Receptors for this molecule have been identified in the hypothalamus, brainstem, and cerebellum in both human and animal models. In rodents, activation of these receptors leads to decreased food intake and reduced body weight [5-7]. Particularly high expression of the proglucagon gene (the precursor of GLP-1) is found in the nucleus of the solitary tract (NTS), which, aside from the hypothalamus, also has extensive connections with the nucleus accumbens (NA) and the ventral tegmental area (VTA) – key regions of the brain's reward system. GLP-1 receptors have been identified in all of these areas, including the hippocampus [8]. These findings support the potential role of GLP-1 analogs in modulating both feeding behavior and reward-related behaviors, including those involved in addiction [9]. This has led to considerable interest in the use of GLP-1 analogs in the treatment of SUDs.

Aim of the study

In recent years, the potential use of GLP-1 analogs in the pharmacotherapy of SUDs has become the subject of numerous studies in both animals and humans [8–10]. The aim of this paper is to review the existing literature on randomized controlled trials (RCTs) evaluating the efficacy of GLP-1 analogs in reducing psychoactive substance use among individuals with SUDs. Most of the studies discussed focus on alcohol use disorder (AUD) and nicotine addiction, although at least one trial involves cocaine use disorder.

Materials and methods

The PubMed database was searched on April 12, 2025, using the following terms: "GLP-1" AND ("addiction" OR "substance use"). Only RCTs assessing the efficacy of glucagon-like peptide-1 receptor (GLP-1R) agonists in reducing addictive behaviors in human subjects with SUD, compared to placebo or other approved therapies for SUD, were included. Articles written in languages other than English, preclinical studies, abstracts, study protocols, review articles, case reports, and case series were excluded. Based on the search strategy described above, a total of 321 papers were retrieved, of which 7 met the inclusion criteria [Table 1]. Full-text access was obtained for all eligible articles. Six of the studies were

randomized, double-blind, placebo-controlled clinical trials; five used a standard parallel-arm design [11–15], and one used a crossover design [16]. The remaining article reported a 12-month follow-up of one of the prior trials [17]. Data were extracted and analyzed using a PICO framework, defining the study population, interventions applied, comparator conditions, and outcomes of interest – namely, the efficacy of GLP-1R agonists in reducing drug consumption and promoting abstinence in individuals with SUD.

Results

A total of 525 adult participants were included in the analysis. Most were diagnosed with nicotine use disorder (NUD; 337 participants) or alcohol use disorder (AUD; 175 participants). Only one small trial investigated the effects of GLP-1R agonists in individuals with cocaine use disorder (13 participants) [16]. One study focused exclusively on overweight and/or prediabetic smokers [14], while another analyzed treatment efficacy in reducing alcohol intake among NUD patients who reported drinking but did not meet diagnostic criteria for AUD [12]. The GLP-1R agonists used included semaglutide (up to 1.0 mg), exenatide (2 mg), and dulaglutide (1.5 mg), administered subcutaneously once weekly, except in one trial that used a single dose of 5 μg exenatide administered subcutaneously prior to cocaine infusion [16]. Control groups received subcutaneous saline injections at the same intervals as experimental groups. Additional interventions in both experimental and control arms included behavioral therapy, brief counseling, or approved medications for NUD. Primary clinical endpoints included self-administration of addictive substances, reduction in heavy drinking days, and abstinence rates at the end of follow-up periods, which ranged from 1 day [16] to 52 weeks [17].

Clinical efficacy

Three of the seven studies reported a significant reduction in substance use according to predefined primary endpoints following treatment with GLP-1R agonists [11, 12, 14], while another reported benefit only in a subgroup of obese participants [13].

In the most recent 2025 study, which used a standardized paradigm to measure voluntary alcohol consumption and the ability to delay drinking, semaglutide significantly reduced the amount of self-administered alcohol compared with placebo. Moderate to large effect sizes were found for both grams of alcohol consumed (β=–0.48, p=0.01) and peak breath alcohol concentration (β=–0.46, p=0.03). Semaglutide also reduced the number of drinks per drinking day (β=–0.41, p=0.04) and weekly alcohol cravings (β=–0.39, p=0.01), although it did not significantly affect total drinks per calendar day or the proportion of drinking to abstinent days. Effect sizes increased over time, indicating progressively greater reductions in heavy drinking days compared to placebo (β=0.84, p=0.04) [11].

Similarly, a predefined secondary analysis of 151 NUD patients who reported drinking at baseline but did not meet criteria for AUD demonstrated benefit with dulaglutide. At week 12, participants receiving 1.5 mg dulaglutide once weekly consumed 29% less alcohol than those receiving placebo (adjusted relative effect=0.71, p=0.04). The mean change in weekly alcohol intake was –1.4 (SD 3.7) drinks in the dulaglutide group vs. –0.1 (SD 6.3) in the placebo group. These effects were independent of baseline consumption and smoking status and were not observed in a small subgroup of 18 heavy drinkers [12].

Conversely, a study evaluating exenatide for AUD found no significant differences in heavy drinking days or total alcohol intake versus placebo during either the 26-week treatment phase or the 6-month follow-up. However, exploratory analyses revealed significant reductions in heavy drinking among participants with BMI>30, suggesting greater responsiveness in this subgroup [13].

A 2021 study focusing exclusively on overweight and/or prediabetic smokers found that those treated with 2 mg exenatide per week were more likely to achieve 7-day smoking abstinence compared to placebo (abstinence rate at 6 weeks: 46.3% vs. 26.8%; RR=1.70, PP=96.5%) [14]. However, positive effects of GLP-1R agonists on NUD were not confirmed in another trial, which investigated dulaglutide's impact on 255 patients with moderate to severe nicotine dependence. At week 12, there were no significant differences in 7-day abstinence rates between treatment and placebo groups. Reductions in craving, daily cigarette use, and end-expiratory CO levels were also comparable [15]. These findings were maintained at the 12-month follow-up [17].

The only study assessing the effects of GLP-1R agonists on cocaine use reported no significant differences between treatment and placebo in cocaine self-administration, self-reported euphoria, or craving following a single exenatide dose [16].

Safety

Adverse events were common in treatment groups but were generally mild and consistent with the known safety profile of GLP-1R agonists. The most frequently reported symptoms were gastrointestinal complaints, followed by weight loss, fatigue,

and transient injection site nodules. Serious adverse events were rare and not attributed to study medications. No adverse interactions were reported between GLP-1R agonists and alcohol, nicotine, cocaine, or other concurrent treatments [11–17].

Discussion

Despite the high prevalence and substantial health burden of SUD, treatment options remain limited and often insufficient. For substances other than alcohol, nicotine, and opioids, no pharmacological treatments have been approved for routine clinical use. GLP-1R agonists, already widely used for metabolic conditions, have been proposed as a novel therapeutic approach for SUD. Encouraging preclinical results [8, 18, 19] led to clinical investigations, and this review summarizes current evidence from RCTs in humans.

Three of the seven reviewed RCTs reported a significant reduction in substance use with GLP-1R ago-

Table 1. Characteristics of individual studies included in the analysis

Author	Participants	Exclusion criteria	Intervention	Comparison	Additional interventions	Follow-up period	Primary outcome	Outcome(s) of interest
Hendershot et al., 2025	48 non-treatment-seeking patients with AUD (DSM-5); • semaglutide (n=24, F=17, mean age=40.6; 23 completed the study) • placebo (n=24, F=17, mean age=39; 19 completed the study)	• age <21 or >65 • consumption of >7 (F) or >14 (M) standard drinks per week and ≥2 heavy drinking episodes in the past month • pre-existing treatment with GLP-1 analogues • current use of weight loss medications • BMI <23 • SUD other than AUD, tobacco use disorder, or mild cannabis use disorder or recent use of illicit drugs (except cannabis) • diabetes and neurological or other medical illness precluding participation	semaglutide sc at weekly dose of 0.25 mg for weeks 1-4, 0.5 mg for weeks 5-8 and 1.0 mg for week 9	placebo once weekly for weeks 1-9	no information	9 weeks	laboratory alcohol self-administration (standardized procedure to assess voluntary alcohol consumption and ability to delay drinking) at week 9	• significant reduction in posttreatment laboratory alcohol self-administration for grams of alcohol consumed (β=−0.48, p=0.01) and peak alcohol breath concentration (β=−0.46, p=0.03) compared to placebo • significant reductions in number of drinks per drinking day (β=−0.41, p =0.04) and in weekly alcohol craving (β =−0.39, p=0.01) • prediction of greater reductions in heavy drinking days over time (β =0.84, p =0.04) compared to placebo
Klausen et al., 2022	127 treatment-seeking patients with AUD (DSM-5); • exenatide (n=62, F=25, mean age=52.1; 32 completed the study) • placebo (n=65, F=26, mean age 52.5; 26 completed the study)	• other SUD • paraclinical tests above the upper limit • CIWA-Ar >9 • AUDIT <15 • record of alcohol-related withdrawal seizures/pancreatitis • <5 heavy drinking days (60/48g of alcohol for M/F) per week in the past 30 days • absence from 1st injection	2 mg of exenatide sc once weekly for 26 weeks	placebo sc once weekly for 26 weeks	standard cognitive-behavioral therapy	26 weeks + 6-month follow-up (55 patients)	reduction in heavy drinking days (recorded with the Time-Line Follow Back)	• no significant difference in number of heavy drinking days and total alcohol intake compared to placebo at 26 weeks and at 6-month follow-up • in subgroup of obese patients (BMI >30) significant reduction of heavy drinking days by 23.6 percentage points and total alcohol intake per 30 days by 1,205g compared to placebo (exploratory analysis)
Lengsfeld et al., 2023	255 patients with at least moderate nicotine dependance; • dulaglutide (n=127, F=83, mean age=42.7; 101 completed the study) • placebo (n=128, F=72, mean age=43.2; 103 completed the study)	• age <18 or >75 • Fagerstroem score <5 • pregnancy • severe renal insufficiency • unstable psychiatric conditions • pre-existing treatment with GLP-1 analogues	1.5 mg of dulaglutide sc once weekly for 12 weeks (reduced dose of 0.75 mg for week 1)	placebo (0.9% NaCl) sc once weekly for 12 weeks	behavioural counselling and 2 mg/day of varenicline po for 12 weeks	12 weeks	point prevalence abstinence rate at week 12 (defined as self-reported 7-days smoking abstinence and end-expiratory exhaled CO ≤10 ppm)	• no difference in abstinence rates at week 12
Luthi et al., 2024	12-month follow-up of patients from Lengsfeld et al. study					52 weeks	point prevalence abstinence rate, prolonged abstinence rate (with abstinence criteria met at previous assessments) and smoking reduction at weeks 24 and 52	• similar declines in point prevalence abstinence rates after 24 and 52 weeks in dulaglutide and placebo group • no significant differences in prolonged abstinence rates at week 24 and 52
Probst et al., 2023	151 patients from Lengsfeld et al. study who consumed alcohol at baseline (median consumption=3 standard glasses per week, IQR 2-7); • - dulaglutide (n=76, F=51, median age=41) • - placebo (n=75, F=41, median age=43)					12 weeks	change in alcohol consumption at week 12	• at week 12 patients on dulaglutide drank an estimated 29% less alcohol (baseline alcohol intake adjusted relative effect=0.71, p=0.04)
Yammine et al., 2021	82 treatment-seeking, prediabetic and/or overweight patients who smoked for ≥1 year (currently ≥10 cigarettes per day); • exenatide (n=41, F=13, mean age=51.0; 34 completed the study) • placebo (n=41, F=12, mean age=51.2; 35 completed the study)	• age <18 or >75 • HbA1c <5.7% or >6.4% • BMI <25 kg/m2 • psychotic or bipolar disorder • moderate to high risk of suicidality • other SUD • personal/family history of medullary thyroid carcinoma or MEN2 syndrome • severe cardiovascular, gastrointestinal of renal disease • DM type 1 • current use of glucose-lowering medications • active temporomandibular joint disease • history/risk of pancreatitis • history of adverse reaction to the medication, nicotine or menthol • pregnancy or lactating	2 mg of exenatide sc once weekly for 6 weeks	placebo (saline) sc once weekly for 6 weeks	• nicotine patches (21 mg) for daily use • brief individual smoking cessation counseling (10-20 min per week)	6 weeks	7-days point prevalence abstinence rate at week 6, defined as self-reported 7-days smoking abstinence and end-expiratory CO ≤5 ppm	• increase in risk for smoking abstinence in exenatide group compared to placebo (46,3% and 26,8%, respectively; RR =1.70, PP =96.5%)
Angarita et al., 2021	13 non-treatment seeking patients (F=1, mean age=45) with moderate to severe CUD (DSM-5)	• age <30 or > 55 • <1 year of CUD • major psychiatric diagnosis unrelated to CUD • history of significant neurological or medical illness • fasting glucose <70mg/dl • current use of psychoactive medications • known hypersensitivity to exenatide • personal/family history of medullary thyroid carcinoma or MEN2 syndrome • positive pregnancy test or breastfeeding	5 μg of exenatide sc in a single dose 3 hours before cocaine self-administration + 90-min period of cocaine self-administration at a required dose (up to 18 infusions of 16 mg/70kg each)	placebo (saline) sc in a single dose 3 hours before cocaine self-administration + 90-min period of cocaine self-administration as in intervention phase	• cocaine training session prior to experimental session • safety eligibility and drug-drug interaction phase (injection of ascending doses of cocaine) • clear liquids with sugar 2 hours before cocaine administration to minimize risk of hypoglycemia	1 day	number of cocaine infusions and subjective effect measured by VAS rating scales	• no significant differences in the number of cocaine infusions and subjective effects compared to placebo

nists compared to placebo [11, 12, 14], while another demonstrated benefit only in a specific subgroup of obese participants [13]. The remaining three studies did not report significant effects; however, two of these were based on the same patient population, with one acting as a 12-month follow-up [15, 17]. The third differed considerably in methodology and had several limitations: a small sample size (13 patients with cocaine use disorder), a single-dose treatment regimen (5 μg exenatide), and a brief observation period of just one day. Additionally, one of its primary endpoints – subjective assessment of cocaine effects via Visual Analog Scales – lacked objectivity, limiting the clinical relevance of its findings [16].

Beyond substance use outcomes, six of the seven studies also assessed metabolic parameters, with each reporting beneficial effects on weight, BMI, or HbA1c levels [11, 13–17], aligning with the known pharmacological profile of GLP-1R agonists. These effects may provide additional benefits for individuals with SUD, who often experience weight gain during early abstinence. Adverse events were mostly mild and gastrointestinal in nature, with no serious treatment-related safety issues or interactions with addictive substances reported. The once-weekly subcutaneous dosing schedule may offer a practical advantage for populations with historically low adherence to treatment.

Conclusions

The available evidence suggests that GLP-1R agonists may represent a promising treatment option for SUD. However, the small number of trials and methodological heterogeneity limit the certainty of conclusions. A meta-analysis may help clarify these preliminary findings. Future research should aim to confirm these results, determine optimal dosing and duration, extend follow-up, and evaluate efficacy for substances beyond alcohol and nicotine. Identification of predictors of treatment response – such as obesity or prediabetes – may support personalized treatment. As of now, five additional clinical trials registered on ClinicalTrials.gov may provide further evidence on the therapeutic potential of GLP-1R agonists.

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