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Pediatric Obesity and GLP-1 Agonist Therapy: Clinical Outcomes of Semaglutide (Wegovy) in Adolescents Aged 12+ with Severe Obesity and Metabolic Comorbidities

Dr. Quoc Dang, DO*

Abstract

Background: Adolescent obesity represents one of the most pressing public health challenges of the current era. Rates of severe obesity in individuals aged 12 to 17 have increased substantially over the past two decades, with associated metabolic comorbidities including insulin resistance, type 2 diabetes, dyslipidemia, and hypertension presenting at younger ages than previously observed. Pharmacological intervention has historically been limited in this population, but the approval of semaglutide 2.4 mg (Wegovy) for adolescents aged 12 and older by the FDA in 2022 marked a significant expansion in available treatment options.

Objective: This review examines the clinical evidence for semaglutide use in adolescents with severe obesity and metabolic comorbidities, with particular attention to the STEP TEENS trial, safety considerations specific to the pediatric population, and implications for clinical practice in pediatric obesity management.

Methods: A narrative review of published clinical trial data, regulatory submissions, and relevant clinical guidelines was conducted. Primary sources included the STEP TEENS randomized controlled trial, FDA prescribing information for semaglutide 2.4 mg in adolescents, and supporting literature on GLP-1 receptor agonist mechanisms in pediatric populations.

Results: The STEP TEENS trial demonstrated that semaglutide 2.4 mg produced a mean reduction in BMI of 16.1% compared to 0.6% in the placebo group at 68 weeks. Approximately 45% of participants achieved a BMI reduction of at least 20%. Improvements were observed across metabolic markers including waist circumference, HbA1c, fasting glucose, and lipid profiles. The side effect profile was consistent with that seen in adult populations, with nausea and vomiting being the most frequently reported adverse events during dose escalation.

Conclusion: Semaglutide represents a clinically meaningful pharmacological option for adolescents aged 12 and older with severe obesity and metabolic comorbidities. Early intervention with effective pharmacotherapy may alter the trajectory of metabolic disease in this population. Ongoing monitoring and individualized clinical management remain essential, and longer-term outcome data in adolescent populations is needed.

Keywords: Pediatric obesity; Semaglutide; Wegovy; GLP-1 receptor agonist; Adolescent; STEP TEENS; Metabolic comorbidities; BMI reduction

Affiliation:
Medical Director, Weightlosspills.com,1521 Alton Road, #729, Miami Beach, FL 33139, USA

***Corresponding author:**
Dr. Quoc Dang, DO, Medical Director, Weightlosspills.com,1521 Alton Road, #729, Miami Beach, FL 33139, USA.

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Introduction

The prevalence of obesity among children and adolescents in the United States and globally has increased at an alarming rate over the past three decades. According to the CDC, approximately 20% of children and adolescents aged 2 to 19 in the United States meet the criteria for obesity, with a substantial subset falling into the category of severe obesity, defined as a BMI at or above 120% of the 95th percentile for age and sex. This population faces disproportionate risk for the early onset of conditions historically considered adult diseases: type 2 diabetes, hypertension, nonalcoholic fatty liver disease, obstructive sleep apnea, and polycystic ovarian syndrome [1].

The clinical management of adolescent obesity has long been constrained by limited pharmacological options. Lifestyle intervention remains the foundation of treatment, but evidence consistently demonstrates that behavioral approaches alone are insufficient for achieving and sustaining meaningful weight reduction in adolescents with severe obesity [2]. Bariatric surgery produces the most durable results in this population but carries procedural risk, requires extensive multidisciplinary evaluation, and remains inaccessible to many due to institutional, geographic, and insurance limitations.

The FDA approval of semaglutide 2.4 mg for chronic weight management in adolescents aged 12 and older, granted in December 2022, represented the first approval of a GLP-1 receptor agonist specifically for weight management in a pediatric population. This approval was based primarily on data from the STEP TEENS trial, a randomized, double blind, placebo controlled study that enrolled adolescents with obesity and at least one weight related comorbidity. The results of this trial, and their implications for clinical practice, warrant careful review.

Background: GLP-1 Receptor Agonism and the Pediatric Patient

GLP-1, or glucagon-like peptide-1, is an incretin hormone secreted by enteroendocrine L cells in the distal small intestine and colon in response to nutrient ingestion. Its primary physiological roles include stimulation of glucose dependent insulin secretion, suppression of glucagon release, slowing of gastric emptying, and centrally mediated reduction of appetite through action on hypothalamic receptors. GLP-1 receptor agonists extend and amplify these effects by binding to the GLP-1 receptor with higher affinity and longer half-life than endogenous GLP-1.

Semaglutide is a long-acting GLP-1 receptor agonist with a plasma half-life of approximately one week, enabling weekly dosing. Its efficacy in adults with obesity has been demonstrated across the STEP trial program, with STEP 1 showing average weight loss of 14.9% of body weight at 68 weeks in adults without diabetes. The mechanism of action is not expected to differ meaningfully between adults and adolescents, though the clinical response and safety considerations in a developing population require independent evaluation [3].

Obesity in adolescence is associated with a substantially elevated risk of adult obesity, cardiovascular disease, type 2 diabetes, and all-cause mortality. The metabolic consequences of adiposity in this age group are compounded by the physiological changes of puberty, including insulin resistance that naturally accompanies pubertal development and may be amplified in the context of obesity. Effective early intervention carries implications not only for immediate health but for the long-term disease trajectory of affected individuals.

STEP TEENS: Trial Design and Primary Outcomes

The STEP TEENS trial (NCT04102189) was a 68-week randomized, double blind, placebo controlled trial enrolling adolescents aged 12 to 17 with a body mass index at or above the 95th percentile for age and sex and at least one weight related comorbidity, or a BMI at or above 40 kg/m2. Participants were randomized 2:1 to receive weekly subcutaneous semaglutide 2.4 mg or placebo, with all participants receiving a background intervention of lifestyle counseling.

The primary endpoint was percentage change in BMI from baseline to week 68. Secondary endpoints included weight change, proportion of participants achieving BMI reductions of at least 5%, 10%, and 20%, and changes in metabolic parameters including HbA1c, fasting plasma glucose, lipids, and blood pressure.

The primary outcome showed a mean BMI reduction of 16.1% in the semaglutide group compared to an increase of 0.6% in the placebo group, a difference of 16.7 percentage points ($p < 0.001$). In absolute terms, participants in the semaglutide arm lost an average of 15.3 kg compared to a gain of 2.4 kg in the placebo arm. With respect to categorical response, 45% of semaglutide-treated participants achieved a BMI reduction of 20% or more, compared to 11% in the placebo group [4].

Metabolic improvements were observed across multiple secondary endpoints. Mean reductions in waist circumference, fasting glucose, HbA1c, total cholesterol, and triglycerides were all significantly greater in the semaglutide arm. Blood pressure reductions were also observed, consistent with findings in adult trials. These metabolic effects are clinically significant in a population where early metabolic deterioration predicts long term cardiovascular and endocrine risk.

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Safety Considerations in Adolescent Populations

The safety profile of semaglutide in STEP TEENS was broadly consistent with observations in adult trials. The most frequently reported adverse events were gastrointestinal in nature: nausea, vomiting, and diarrhea were more common in the semaglutide group during the dose escalation phase and generally decreased in frequency as patients remained on a stable dose. Serious adverse events were reported in 11% of the semaglutide group and 9.6% of the placebo group; the difference was not statistically significant and no new safety signals specific to the adolescent population were identified.

Particular attention has been given to the potential effects of GLP-1 receptor agonism on growth and bone density in adolescents, given the ongoing development during this life stage. The STEP TEENS trial was not powered or designed with sufficient duration to evaluate these endpoints comprehensively. Post-marketing surveillance and longer-term follow-up studies are necessary to characterize these risks, and clinicians prescribing semaglutide to adolescents should maintain awareness of this gap in the evidence base [5].

The contraindication profile mirrors that of adult use: patients with a personal or family history of medullary thyroid carcinoma or multiple endocrine neoplasia type 2 should not receive semaglutide. The rodent thyroid C-cell tumor signal observed in preclinical studies has not been confirmed in human data; however, the contraindication is maintained and assumes particular importance in a pediatric population where long-term exposure begins earlier in life.

Clinical Implications and Prescribing Considerations

The STEP TEENS data support the integration of semaglutide into the treatment algorithm for adolescents aged 12 and older with severe obesity and metabolic comorbidities when lifestyle intervention has been insufficient. Several practical considerations inform how this should be implemented in clinical practice [6].

Patient and family engagement is important in a way that differs somewhat from adult prescribing. Adolescent adherence to weekly injections requires family support, and realistic expectations about the adjustment period during dose escalation should be communicated to both patients and caregivers. The nausea associated with early treatment is manageable with dietary modification but needs to be anticipated.

Long-term therapy should be framing from the outset. Discontinuation studies in adult populations have consistently shown weight regain following cessation of GLP-1 receptor agonist therapy, and there is no reason to expect this pattern to differ in adolescents [7]. Initiating treatment with an explicit understanding that this represents ongoing chronic disease management, rather than a time-limited intervention, is important for appropriate expectations and treatment planning [8].

Access and coverage represent a significant practical barrier. Semaglutide 2.4 mg carries a substantial list price, and coverage for pediatric obesity pharmacotherapy is inconsistent across commercial insurance plans and state Medicaid programs. Clinicians should be familiar with manufacturer patient assistance programs and be prepared to support prior authorization requests with thorough documentation of medical necessity.

Conclusion

Adolescent obesity with metabolic comorbidities represents a high-stakes clinical problem with historically limited pharmacological solutions. The STEP TEENS trial provides robust evidence that semaglutide 2.4 mg produces clinically meaningful BMI reduction and metabolic improvement in adolescents aged 12 and older, with a safety profile consistent with adult experience. The FDA approval of this indication offers clinicians a meaningful addition to the treatment toolkit for this challenging population.

Longer-term data on durability, growth effects, bone density, and cardiovascular outcomes in adolescent populations will be needed to fully characterize the benefit-risk profile of extended treatment. In the interim, individualized clinical judgment, thorough patient and family counseling, and consistent follow-up remain essential components of effective management.

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