Weekly growth hormone therapy: a safer path to long-term height gains?

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Growth hormone deficiency (GHD) in children presents a significant clinical challenge, primarily manifesting as short stature and delayed development. The established standard of care involves daily subcutaneous injections of recombinant human growth hormone (rhGH), a regimen that, while effective, places a considerable burden on patients and their families, often leading to adherence issues over years of treatment.

The prospect of a less frequent dosing schedule has long been a goal for endocrinologists, aiming to improve quality of life without compromising efficacy or safety. Weekly formulations of rhGH have emerged as a potential solution, offering a more convenient option for long-term management.

KEY TAKEAWAYS

- The Pivot: Weekly growth hormone formulations aim to reduce injection frequency, addressing a major barrier to adherence in pediatric GHD.
- The Data: These therapies demonstrate comparable efficacy to daily injections in promoting linear growth, with similar safety profiles.
- The Action: Clinicians should consider weekly rhGH as a viable option for children requiring long-term growth hormone therapy, particularly where adherence to daily regimens is a concern.

Childhood growth hormone deficiency is a condition characterized by inadequate secretion of growth hormone from the pituitary gland, leading to impaired linear growth and short stature. Beyond the obvious physical manifestation, GHD can impact bone mineral density, body composition, and overall quality of life. Early diagnosis and intervention are critical to maximizing final adult height, but the journey is often protracted, spanning many years of treatment.

The conventional approach to GHD management involves daily subcutaneous injections of recombinant human growth hormone. This regimen, while clinically effective, demands consistent administration, often by parents or caregivers, for the entirety of a child's growth period. The daily needle stick can be a source of significant psychological distress for children and a logistical challenge for families, contributing to poor adherence and, consequently, suboptimal treatment outcomes. The unmet need for a less burdensome, yet equally effective, treatment modality has driven the development of long-acting growth hormone formulations.

The Mechanism of Action and Formulation

Growth hormone, a peptide hormone, exerts its effects primarily by stimulating the liver and other tissues to produce insulin-like growth factor 1 (IGF-1). IGF-1, in turn, promotes the proliferation of chondrocytes in the epiphyseal growth plates, leading to linear bone growth. It also influences protein synthesis, lipolysis, and glucose metabolism. The

challenge with developing a weekly formulation lies in maintaining a consistent therapeutic level of growth hormone over an extended period without causing excessive peaks or troughs in concentration.

Various strategies have been employed to achieve this sustained release. One common method involves pegylation, where polyethylene glycol (PEG) molecules are attached to the growth hormone molecule. This increases the molecular size, reduces renal clearance, and protects the hormone from enzymatic degradation, thereby extending its half-life. Other approaches include fusion proteins, where growth hormone is linked to a carrier protein like albumin or an Fc fragment of an immunoglobulin, or encapsulation in biodegradable microspheres. The goal is to mimic the physiological pulsatile release of growth hormone as closely as possible, but over a longer interval, typically once a week.

Patient Populations and Treatment Goals

Weekly growth hormone therapy is primarily indicated for pediatric patients diagnosed with growth hormone deficiency. This diagnosis typically relies on a combination of clinical assessment, auxological data (height velocity, bone age), and biochemical tests, including growth hormone stimulation tests and IGF-1 levels. The treatment aims to normalize growth velocity, achieve an adult height within the target range predicted by parental heights, and improve body composition. It is not a therapy for idiopathic short stature without confirmed GHD, nor is it a cosmetic intervention.

The patient population for weekly formulations is largely the same as for daily rhGH, but with an added emphasis on those who may benefit most from reduced injection frequency. This includes younger children who may experience greater distress with daily injections, adolescents who may struggle with adherence due to increasing independence and social pressures, and families with complex schedules or travel requirements. The convenience factor is a significant driver for adoption in these groups, potentially leading to better long-term compliance and, by extension, better clinical outcomes.

Clinical Efficacy and Safety Profile

Clinical investigations into weekly growth hormone formulations have consistently focused on demonstrating non-inferiority to daily rhGH in terms of efficacy, primarily measured by annualized height velocity (AHV) and changes in height standard deviation score (SDS). These studies typically involve a randomized, open-label design, comparing a weekly regimen to a daily regimen over a period of 6 to 12 months, followed by an extension phase to assess long-term safety and efficacy.

The data generally show that weekly growth hormone therapy achieves comparable improvements in AHV and height SDS to daily therapy. Children receiving weekly injections exhibit similar growth rates, suggesting that the less frequent dosing does not compromise the primary therapeutic goal of linear growth promotion. The sustained release profile of these weekly formulations ensures that IGF-1 levels remain within the physiological range, avoiding the supraphysiological peaks sometimes associated with daily injections, which could theoretically lead to adverse effects.

Safety is paramount in pediatric treatments, especially those administered over many years. The safety profile of weekly growth hormone formulations has been found to be largely consistent with that of daily rhGH. Common adverse events include injection site reactions, such as pain, redness, or swelling, which are generally mild and transient. Other reported side effects are similar to those seen with daily growth hormone, including headache, arthralgia, and myalgia. There has been no evidence of increased risk of serious adverse events, such as malignancy or glucose intolerance, with weekly formulations compared to daily ones. Regular monitoring of IGF-1 levels, thyroid function, and glucose metabolism

remains essential, as with any growth hormone therapy. The Oxford Handbook of Endocrinology and Diabetes offers a practical guide to managing these complex endocrine conditions.

Long-Term Outcomes and Adherence

The true measure of success for GHD therapy is the final adult height achieved and the overall impact on patient well-being. While initial studies focus on short-term growth velocity, longer-term data are crucial to confirm sustained efficacy and safety. Extension phases of clinical trials have followed patients for several years, demonstrating that the height gains achieved with weekly therapy are maintained over time, leading to appropriate final adult heights. This sustained efficacy is critical for a condition requiring treatment throughout childhood and adolescence.

But the real advantage of weekly growth hormone therapy lies in its potential to improve adherence. The reduction from 365 injections per year to 52 injections per year is a substantial decrease in treatment burden. Improved adherence directly translates to better clinical outcomes, as missed doses can significantly impair growth velocity. Anecdotal evidence and patient-reported outcomes suggest a higher satisfaction rate and a greater willingness to continue therapy with weekly regimens. This is not merely a matter of convenience; it is a direct pathway to more consistent treatment and, therefore, better long-term height outcomes for children with GHD.

Where it Falls Short

Despite the clear advantages, weekly growth hormone therapy is not without its considerations. The primary caveat often revolves around the cost. Long-acting formulations typically carry a higher price tag than their daily counterparts, which can be a barrier to access in some healthcare systems. Reimbursement policies and national guidelines play a significant role in determining the availability and uptake of these newer therapies. While the cost per injection is higher, the overall cost-effectiveness must also factor in improved adherence and potentially better long-term outcomes, which could reduce healthcare resource utilization in other areas.

Another point of discussion is the pharmacokinetic and pharmacodynamic profile. While weekly formulations aim for sustained release, the peak-to-trough ratio might differ from daily injections, which more closely mimic the physiological pulsatile release. The clinical significance of these differences is still under investigation, but current data suggest no adverse impact on growth or safety. The long-term effects on bone health, body composition, and metabolic parameters also require continued surveillance, although existing data are reassuring.

The choice between daily and weekly growth hormone therapy ultimately involves a shared decision-making process between the clinician, the patient, and their family. Factors such as patient age, individual preferences, lifestyle, and potential adherence challenges must be weighed against the clinical data. For many, the reduction in injection frequency will be a compelling argument, but for others, the established track record and lower cost of daily therapy may still be preferred. The availability of both options allows for a more personalized approach to GHD management.

> **CLINICAL IMPLICATIONS**
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> The advent of weekly growth hormone therapy marks a meaningful step forward in pediatric endocrinology. For clinicians, this offers a genuine alternative to the daily injection regimen, which has historically been a source of frustration for both patients and prescribers due to adherence challenges. We can now offer a treatment that is not just effective, but also significantly less burdensome, potentially leading to more consistent therapy

and better final height outcomes.

But the conversation with families must be transparent. While the convenience factor is substantial, the higher cost of these long-acting formulations cannot be ignored. Clinicians must be prepared to discuss the trade-offs between cost, convenience, and the established long-term data for daily injections. This is not a one-size-fits-all solution, but rather an expansion of our therapeutic toolkit.

The industry's focus on patient-centric solutions, driven by the clear unmet need for improved adherence, is commendable. The development of these weekly formulations demonstrates that innovation can extend beyond pure efficacy to address the practical realities of living with a chronic condition. Future research should continue to explore even longer-acting formulations and further refine the pharmacokinetic profiles to optimize physiological mimicry.

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