



Effect of Growth Hormone Therapy on Growth Velocity, Insulin-like Growth Factor-1 Level, and Bone Age in Growth Hormone Deficient Children in Sulaymaniyah City,

Iraq

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Abstract

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BACKGROUND: One of the significant causes of short stature is Growth hormone deficiency (GHD). While recombinant human growth hormone (rhGH) therapy is effective, region-specific data from Iraq is limited. This study evaluated the effect of rhGH therapy on growth velocity, insulin-like growth factor-1 (IGF-1) levels, and advancement in bone age in Iraqi children with GHD. **MATERIALS AND METHODS:** A retrospective cohort study was conducted on 100 children with confirmed GHD (57 males, 43 females; mean age 9.7±2.7 years) who were treated with rhGH (mean dose 0.037 mg/kg/day) at Sulaymaniyah Teaching Hospital. Growth velocity, IGF-1 standard deviation scores (SDS), and bone age were assessed at baseline and over two years of therapy. Statistical analysis employed paired t-tests, correlation analysis, and subgroup comparisons. **RESULTS:** Growth velocity significantly increased from a baseline of 2.51±1.44 cm/year to 4.93±1.93 cm/year at 1 year and 5.35±1.80 cm/year at 2 years ($p<0.001$ for all). IGF-1 SDS normalized rapidly, from -1.57±1.35 at baseline to -0.06±1.05 at 1 month and 1.04±0.71 at 1 year ($p<0.001$). Bone age advanced by 1.07±0.59 years in the first year (slightly faster than chronological age, $p<0.001$) but by only 1.46±0.81 years over two years, resulting in a favorable net advancement rate of 0.73 years per chronological year ($p<0.001$). A significant correlation was found between Δ IGF-1 SDS and Δ growth velocity ($r=0.300$, $p=0.002$). Males showed a significantly better growth response than females ($p=0.040$). **CONCLUSIONS:** rhGH therapy is highly effective and safe for Iraqi children with GHD, leading to significant improvements in growth velocity and normalization of IGF-1 levels without premature acceleration of skeletal maturation. These findings provide crucial local evidence to support and optimize treatment protocols in Iraq.

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1. Introduction

Growth hormone deficiency (GHD) is a rare endocrine disorder characterized by inadequate secretion of growth hormone (GH) from the anterior pituitary gland, leading to significant growth failure and short stature in children¹. Estimated global incidence of deficiency ranges from 1:4,000 to 1:10,000 live births². The diagnosis requires a comprehensive evaluation, including auxological assessment, biochemical testing with GH stimulation tests, and radiological evaluation of bone age³. The standard treatment is daily subcutaneous injections of recombinant human growth hormone (rhGH), which aims to normalize growth velocity, achieve catch-up growth, and attain a final adult height inside the ranges of the genetic target⁴.

The efficacy of rhGH therapy is well-established in Western populations, demonstrating significant improvements in growth velocity and final adult height^{5,6}. However, the response to treatment can be influenced by several factors such as ethnicity, environmental conditions, and healthcare infrastructure⁷. There is a notable paucity of comprehensive data on outcomes of rhGH therapy from the Middle East, particularly Iraq⁸. While some studies have examined growth velocity, few have concurrently assessed the crucial interrelated parameters of IGF-1 levels and bone age advancement in this population⁹. Our study aimed to comprehensively evaluate and assess the effect of rhGH therapy on growth velocity, IGF-1 levels, and bone age advancement in a cohort of children with GHD in Sulaymaniyah, Iraq.

2. Materials and Methods

2.1 Study Design and Population

A retrospective cohort study was conducted on 100 children with confirmed GHD who received rhGH therapy at the Pediatric Outpatient Endocrinology Clinic of Sulaymaniyah Teaching Hospital. The diagnosis of GHD was based on: (1) height below -2 SD for age and sex; (2) growth velocity below the 25th percentile; (3) delayed bone age (>1 year behind chronological age); and (4) peak GH level <10 ng/mL on two separate growth hormone stimulation tests. Children with syndromic short stature, chronic illnesses, or poor treatment adherence were excluded.

2.2 Data Collection

Baseline demographic, clinical, and biochemical data were extracted from medical records. The primary outcome measures were:

1. **Growth Velocity (cm/year):** Calculated from serial height measurements.
2. **IGF-1 Standard Deviation Score (SDS):** Measured by chemiluminescence immunoassay.
3. **Bone Age (BA):** Assessed from left hand-wrist radiographs using the Greulich-Pyle method.

These parameters evaluated at baseline, 1 months, 6 months, 1 year, and 2 years after initiating rhGH therapy.

2.3 Statistical Analysis:

The collected data were analysed using the SPSS program version 26.0. Continuous variables were presented as mean \pm standard deviation or median [interquartile range]. All the Changes from baseline were analysed using paired samples t-tests. The relationships between different variables were assessed using the Spearman's correlation coefficient (r^*s^*). Subgroup comparisons were performed using the Mann-Whitney U test. A p-value <0.05 was considered statistically significant.

3. Results

3.1 Baseline Characteristics:

The cohort consisted of 100 children (57% male) with a mean age at diagnosis of 9.7 ± 2.7 years. Baseline characteristics are summarized in Table 1. The mean baseline growth velocity was 2.51 ± 1.44 cm/year, and the mean bone age delay was 1.3 ± 1.83 years. The mean baseline IGF-1 SDS was -1.57 ± 1.35 , confirming biochemical deficiency.

Table 1. Baseline Demographic and Clinical Characteristics (N=100)

| Variable | Value |
|------------------------------------|-------------------|
| Age at diagnosis (years) | 9.7 ± 2.7 |
| Gender, n (%) Male | 57 (57%) |
| Female | 43 (43%) |
| Baseline Growth Velocity (cm/year) | 2.51 ± 1.44 |
| Baseline GH Doses (mg/kg/day) | 0.037 ± 0.003 |
| Bone Age Delay (years) | 1.3 ± 1.83 |
| Baseline IGF-1 SDS | -1.57 ± 1.35 |

Effect on Growth Velocity:

Use of rhGH therapy were resulted in highly significant increase in the growth velocity (Table 2). The mean increase from baseline was 1.30 cm/year (95% CI: 1.05 to 1.56) at 6 months, 2.42 cm/year (95% CI: 2.06 to 2.79) at 1 year, and 2.85 cm/year (95% CI: 2.49 to 3.20) at 2 years ($p < 0.001$ for all).

Table 2. Changes in Growth Velocity During GH Therapy

| Time | Mean GV (cm/year) | Median GV | Mean Difference from Baseline | p- |
|-----------------|-------------------|------------------|-------------------------------|--------|
| Point | ± SD | [IQR] | (95% CI) | value |
| Baseline | 2.51 ± 1.44 | 2.00 [1.50-2.50] | - | - |
| 6 Months | 3.81 ± 1.59 | 3.50 [2.50-5.00] | 1.30 (1.05 to 1.56) | <0.001 |
| 1 Year | 4.93 ± 1.93 | 5.00 [4.00-6.40] | 2.42 (2.06 to 2.79) | <0.001 |
| 2 Years | 5.35 ± 1.80 | 5.35 [4.50-5.90] | 2.85 (2.49 to 3.20) | <0.001 |

3.2 Effect on IGF-1 Levels:

IGF-1 levels normalized rapidly (Table 3). The mean IGF-1 SDS increased by 1.51 (95% CI: 1.27 to 1.75) within one month of treatment ($p < 0.001$) and was sustained within the mid-to-high normal range (SDS 1.04 ± 0.71) at one year.

Table 3. Changes in IGF-1 SDS during GH Therapy

| Time | Mean IGF-1 | Median IGF-1 SDS | Mean Difference from Baseline | p-value |
|-----------------|--------------|--------------------|-------------------------------|---------|
| Point | SDS ± SD | [IQR] | (95% CI) | |
| Baseline | -1.57 ± 1.35 | -2.00 [-3.00-0.00] | - | - |
| 1 Month | -0.06 ± 1.05 | 0.00 [-1.00-1.00] | 1.51 (1.27 to 1.75) | <0.001 |
| 6 Months | 0.59 ± 0.82 | 1.00 [0.00-1.00] | 2.16 (1.90 to 2.42) | <0.001 |
| 1 Year | 1.04 ± 0.71 | 1.00 [1.00-2.00] | 2.61 (2.34 to 2.88) | <0.001 |

3.3 Effect on Bone Age:

Bone age advanced by 1.07 ± 0.59 years in the first year (ratio to chronological age: 1.07, $p < 0.001$). Over the full two-year period, the total advancement was 1.46 ± 0.81 years against 2.0 chronological years, resulting in a significantly reduced ratio of 0.73 ($p < 0.001$), indicating preservation of growth potential.

3.4 Correlations and Subgroup Analysis:

The study found significant positive correlation between the change in IGF-1 SDS and the change in growth velocity at one year ($r^*s^* = 0.300$, $p = 0.002$). Subgroup analysis revealed that male patients had a significantly greater growth response than females (median Δ GV: 2.50 vs. 2.00 cm/year, $p = 0.040$). Age and baseline severity showed no significant difference in response.

4. Discussion

This study provides comprehensive regional data demonstrating the high efficacy and safety of recombinant human growth hormone (rhGH) therapy for children in the Republic of Iraq presenting with GHD. The overall mean observed increase in growth velocity of 2.85 cm/year after two years of treatment is consistent with results from international studies and meta-analyses, which report first-year gains of approximately 3-4 cm/year⁵⁶¹⁰. The rapid normalization of IGF-1 levels within one month of treatment confirms effective biochemical replacement and aligns with the known pharmacodynamics of rhGH¹¹. The significant correlation between the increase in IGF-1 and the improvement in growth velocity ($r=0.300$, $p=0.002$) reinforces the central role of the GH-IGF-1 axis in mediating the growth response to therapy¹².

A crucial finding of this study is the favorable pattern of bone age advancement. The initial slight catch-up in the maturation of skeletal development in the first year was followed by a rate of advancement that was significantly slower than chronological time over the two-year period. This pattern is ideal, as it indicates that therapy promotes substantial linear growth without prematurely depleting future growth potential, a balance essential for optimizing final height outcomes¹³.

The better growth response observed in males compared to females is an interesting finding that warrants further investigation with larger sample sizes. It may be related to differences in pubertal timing, body composition, or societal factors influencing nutrition and treatment adherence.

5. Limitations:

The retrospective design is subject to potential information bias. The lack of availability of a control group and the relatively short duration of follow-up limit the assessment of long-term outcomes like final adult height. Additionally, the single-center design may affect generalizability.

6. Conclusion

rhGH therapy is a potent and safe intervention for children with GHD in Iraq, leading to rapid normalization of IGF-1 levels, significant catch-up growth, and a favorable bone maturation pattern that preserves future growth potential. The study findings underscore the importance of early diagnosis of GHD and early treatment initiation. This study provides robust local evidence to guide clinical practice and optimize treatment protocols for GHD in Iraq and similar healthcare settings.

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