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EVALUATION OF RECOMBINANT GROWTH HORMONE THERAPY OUTCOMES ON CHILDREN WITH SHORT STATURE IN NINEVEH GOVERNORATE

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ABSTRACT

Background: Short stature is a common pediatric condition affecting growth and quality of life. Recombinant growth hormone therapy (rGHT) is widely used, although treatment response varies according to the underlying etiology. **Aim:** To evaluate the outcomes of recombinant growth hormone therapy in children with short stature treated at Al Wafaa Tertiary Center in Nineveh Governorate. **Methods:** This cross-sectional study included 300 children and adolescents with short stature who had received rGHT for at least one year. Data were collected from medical records and structured interviews with patients or caregivers. **Results:** Growth hormone deficiency (GHD) was the most common indication for treatment. Children with GHD demonstrated a significant increase in mean height from 124.85 to 131.33 cm after one year of therapy ($p < 0.001$) and significant weight gain ($p < 0.001$). In contrast, height improvement was not significant in idiopathic short stature (ISS; $p = 0.075$) or Turner syndrome (TS; $p = 0.101$). Weight increased significantly in ISS ($p = 0.027$) but not in TS ($p = 0.148$). Adverse events were uncommon, with joint pain (7%) and headache (4.49%) being the most frequent. Over 90% of children with GHD reported no treatment-related side effects. **Conclusion:** Recombinant growth hormone therapy was most effective in children with GHD, producing significant improvements in height and weight with minimal adverse effects. Benefits were modest in ISS and limited in TS, highlighting the importance of early diagnosis and individualized treatment strategies.

KEYWORDS: Short stature; Recombinant growth hormone therapy; Growth hormone deficiency; Turner syndrome; Children. and secretes growth hormone (GH), which affects tissue growth.

1. INTRODUCTION

Short stature, by definition, is a height that is more than 2 standard deviations (SD) below the mean for age, sex, and population, or a height below the 3rd percentile, with some sources also considering a fall in growth velocity below the 25th percentile as significant.[1]

1.1 Recombinant growth hormone therapy background

A single-chain polypeptide consisting of 21 amino acids makes up growth hormone (GH). The anterior pituitary gland produces and metabolism[2,3] and helps in the regulation of bone, muscle, and liver tissue functions.[4,5] It achieves this through insulin-like growth factor-1 (IGF-1). Therefore, any growth axis abnormality or damage will result in inappropriate or reduced GH secretion, which will ultimately lead to short stature.

1.2 Indications of recombinant growth hormone therapy

At the beginning of rGHT use, it was only given to children with short stature due to growth hormone deficiency (GHD), then its use expanded to include other causes of short stature, such as idiopathic short stature (ISS), Turner syndrome (TS), Prader-Willi syndrome (PWS), chronic kidney disease (CKD), small for gestational age (SGA), and Noonan syndrome (NS).[6]

After (rGH) therapy started, several observational studies were done to evaluate its effect on children.[7,8]

Additionally, growth hormone therapy has been confirmed to improve the final height based on the indications mentioned above.[7, 8, 9]

However, despite the abundance of literature on the use and effects of rGHT, limited information and data are available for rGHT in the Middle East and Nineveh, which share distinct sociocultural and ethnic pasts.

1.3 Side effects of rGHT

The safety and efficacy of GH treatment in children have been widely investigated, but the long-term effects and potential risks remain unknown since recombinant GH became commercially available in 1985.[10,11,12] Many of these studies were industry-sponsored post-marketing surveillance studies, which lacked both control groups for comparison and long-term follow-up following medication termination.

1.4 When to start and when to stop growth hormone therapy

Earlier initiation of GH therapy is associated with better height outcomes, while delayed treatment, especially after puberty, reduces its effectiveness. Continuation or discontinuation of therapy should be individualized according to growth response, remaining growth potential, and patient-specific factors.[13,14]

1.5 Aim of the Study

This study aims to evaluate the outcomes of recombinant growth hormone therapy outcomes on children with short stature at Al Wafaa Tertiary Center in Nineveh Governorate.

1.6 Specific Objectives

1. Describe demographic characteristics of the studied sample.
2. To identify the increase in height and weight of children who have been taking rGHT for more than 1 year.
3. To demonstrate any side effects of therapy on children taking it.
4. To assess the psychological and social impact of rGHT on children while taking it.
5. To find the association of age at initiation of treatment, adherence to therapy, and initial diagnosis with treatment outcomes.

2. Study Setting and Design

This study is a cross-sectional review of children and adolescents treated with rGHT.

A pilot study was conducted on 20 children with short stature receiving recombinant growth hormone therapy at the Al- Wafaa Center for Diabetes and Endocrinology in Nineveh Governorate. The aim was to evaluate the clarity and feasibility of the data collection tool and to identify potential challenges before the main study.

The response rate was 95%, as one parent declined participation. Minor modifications were made to the questionnaire to simplify certain medical terms and enhance parental understanding. The pilot confirmed that the study design and data collection procedures were appropriate and feasible.

2.1 Study Period

The study was conducted between January 2025 and June 2025, whereas data collection lasted 4 months from February 2025.

2.2 Study Sample and Sampling Technique

A convenient sampling method was used where all patients who fulfilled the inclusion criteria were included in the study.

Inclusion criteria: All children with short stature who have been diagnosed by a pediatrician or endocrinologist, who are attending Al Wafaa Center, male and female, with different indications, who have been taking rGH for 1 year or more, will be included in the study.

Exclusion Criteria: children taking rGH for less than 1 year.

2.3 Data Collection Tool

Data were collected using a standardized data collection form based on patients' medical records and interviews with patients and/or their parents. The tool included demographic characteristics, baseline and one-year follow-up anthropometric measurements (height and weight), treatment indication, adherence to recombinant growth hormone therapy, follow-up visits, adverse effects, and the social and psychological impact of treatment. Patients were classified into three groups according to treatment indication: Growth Hormone Deficiency (GHD), Turner Syndrome (TS), and Idiopathic Short Stature (ISS). Adherence and follow-up data were obtained from medical records, while changes in self-esteem, social interactions, mood, and behavior were assessed through structured interviews.

3. Statistical Analysis

Data were analyzed using the Statistical Package for the Social Sciences (SPSS), version 30.0 (IBM Corp., Armonk, NY, USA). Continuous variables were presented as mean ± standard deviation (SD), while categorical variables were expressed as frequencies and percentages. Independent-samples t-tests were used to compare treatment outcomes between two independent groups. Simple and multiple linear regression analyses were performed to evaluate the effects of age at treatment initiation, treatment adherence, and initial diagnosis on height after one year of recombinant growth hormone therapy (rGHT). Regression coefficients (α and β) with their corresponding P-values were reported. A two-tailed P-value of < 0.05 was considered statistically significant.

3.1 Analytic statistics

- An independent-samples t-test was used to compare continuous variables between two independent groups.
- Simple and multiple linear regression analyses were performed to evaluate the effects of age at treatment initiation, adherence, and initial diagnosis on treatment outcomes.
- A P-value of < 0.05 was considered statistically significant.

Level of significance

For all the above-mentioned statistical tests, the level of significance was set at 5% (p-value).

- p-value >0.05 indicates a non-significant result.
- p-value ≤ 0.05 indicates a significant result.
- p-value ≤ 0.01 indicates a highly significant result.
- p-value ≤ 0.001 indicates a very highly significant result.

4. RESULTS

The baseline demographic characteristics of the study population are presented in Table 1. The table summarizes the distribution of participants according to diagnosis, age group, sex, and place of residence. A total of 300 children were included in the study and categorized into three diagnostic groups: growth hormone deficiency (GHD), idiopathic short stature (ISS), and Turner syndrome (TS). The demographic profile demonstrates variations in age distribution, sex, and residential status among the study groups.

Table 2 presents the changes in height (cm) and height standard deviation score (Height SDS) before and after recombinant growth hormone therapy (rGHT) among the different treatment indications.

Table 3 presents the changes in body weight (kg) and weight standard deviation score (Weight SDS) before and after rGHT across the different treatment indications.

Table 1: Demographic characteristics of the sample.

Variable	Category		GHD	ISS	TS	Total
Age	≤10	No.	67	32	5	104
		%	34.18%	43.24%	16.67%	34.67%
	>10	No.	129	42	25	196
		%	65.82%	56.76%	83.33%	65.33%
Gender	Male	No.	95	43	0	138
		%	48.47%	58.11%	0.00%	46.00%
	Female	No.	101	31	30	162
		%	51.53%	41.89%	100.00%	54.00%
Residency	Urban	No.	142	49	15	206
		%	72.45%	66.22%	50.00%	68.67%
	Sub-Urban	No.	48	19	12	79
		%	24.49%	25.68%	40.00%	26.33%
	Rural	No.	6	6	3	15
		%	3.06%	8.11%	10.00%	5.00%
Total		No.	196	74	30	300
		%	65.33%	24.67%	10.00%	100%

Table 2: Height changes of the patients before and after one year of treatment.

Indication	Mean before	SD before	SDS before	Mean after	SD after	SDS after	t-value	p-value
GHD	124.847	13.970	M: -2.72 / F: -3.03	131.332	13.910	M: -2.27 / F: -2.77	-4.610	< 0.001
ISS	124.473	13.793	M: -2.78 / F: -3.06	128.554	13.915	M: -2.52 / F: -3.05	-1.790	0.075
TS	125.333	13.363	F: -3.43	130.867	12.328	F: -3.19	-1.670	0.101
Total	124.803	13.824	—	130.600	13.769	—	—	—

Table 3: Weight changes of the patients before and after one year of treatment.

Indication	Mean before	SD before	SDS before	Mean after	SD after	SDS after	t-value	p-value
GHD	26.189	8.367	M: -1.35 / F: -1.37	30.133	9.795	M: -1.13 / F: -1.22	-4.290	< 0.001
ISS	24.703	7.692	M: -1.47 / F: -1.48	27.662	8.453	M: -1.39 / F: -1.46	-2.230	0.027
TS	34.600	10.183	F: -0.67	38.533	10.576	F: -0.63	-1.470	0.148

Total	26.663	8.808	—	30.363	9.970	—	—	—

Table 4 presents the comparison of age, height after one year of recombinant growth hormone therapy (rGHT), and body weight after one year between patients with growth hormone deficiency (GHD) and idiopathic short stature (ISS). Independent sample t-tests were performed to evaluate differences between the two groups in these clinical parameters.

Table 5 presents the comparison of age, height after one year of recombinant growth hormone therapy (rGHT), and body weight after one year between patients with growth hormone deficiency (GHD) and Turner syndrome (TS). Independent sample t-tests were performed to evaluate differences between the two groups in these clinical parameters.

Table 6 presents the effect of recombinant growth hormone therapy (rGHT) on patients' mood and behavior. The table summarizes the reported changes in mood and behavioral status following treatment, including improvement, worsening, or no noticeable change, thereby providing an overview of the psychological and behavioral outcomes associated with rGHT

Table 4: Treatment outcomes comparison between GHD patients and ISS patients.

Parameters	GHD (n=196) Mean	GHD SD	ISS (n=74) Mean	ISS SD	t-value	p-value
Age after one year	12.066	2.60	11.878	2.77	-0.45	0.653
Height after one year	131.332	13.910	128.554	13.915	-11.50	< 0.001
Weight after one year	30.133	9.795	27.662	8.453	-3.60	< 0.001

Table 5: Treatment outcome comparison between GHD patients and TS patients.

Parameters	GHD (n=196) Mean	GHD SD	TS (n=30) Mean	TS SD	t-value	p-value
Age after one year	12.066	2.60	12.900	2.56	1.08	0.287
Height after one year	131.332	13.910	130.867	2.328	-2.21	0.033
Weight after one year	30.133	9.795	38.533	10.576	-0.03	0.977

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Table 6: The effect of rGHT on the mood and behavior of patients through different indications.

Indication	Improved No.	Improved %	Worse No.	Worse %	No change.	No Change %	Total
GHD	96	48.98%	12	13.64%	88	44.90%	196
ISS	12	16.22%	24	63.16%	38	51.35%	74
TS	9	30.00%	7	50.00%	14	46.67%	30
Total	117	39.00%	43	30.71%	140	46.67%	300

Table 7 presents the changes in self-esteem and social life after one year of recombinant growth hormone therapy (rGHT) among patients with different treatment indications. The table summarizes the reported psychosocial outcomes across the diagnostic groups, providing an overview of the impact of rGHT on patients' self-esteem and social functioning following treatment.

Table 8 presents the reported adverse effects following one year of recombinant growth hormone therapy (rGHT) among patients with different treatment indications. The table summarizes the frequency of treatment-related side effects, including joint pain and headache, across the diagnostic groups, providing an overview of the safety and tolerability of rGHT during the study period.

Table 9 presents the follow-up and monitoring schedule of patients during the first year of recombinant growth hormone therapy (rGHT) according to the different treatment indications. The table summarizes the frequency of clinical follow-up visits among the diagnostic groups, providing an overview of patient monitoring practices throughout the treatment period.

Table 7: The effect of rGHT on self-esteem and social life of patients through different indications.

Indication	Yes No.	Yes %	No No.	No %	Total
GHD	69	35.20%	127	64.80%	196
ISS	7	9.46%	67	90.54%	74
TS	10	33.33%	20	66.67%	30
Total	86	28.67%	214	71.33%	300

Table 8: The description of the side effects of rGHT during one year of treatment.

Indication	Joint pain: No.	Joint pain %	Headache No.	Headache %	Nothing No.	Nothing %	Total
GHD	11	5.61%	8	4.52%	177	90.31%	196
ISS	5	6.76%	1	1.47%	68	91.89%	74
TS	5	16.67%	3	13.64%	22	73.33%	30
Total	21	7.00%	12	4.49%	267	89.00%	300

Table 9: Description of patients' follow-up during one year of treatment.

Indication	3 Months No.	3 Months %	6 Months No.	6 Months %	Annual No.	Annual %	Total
GHD	175	89.29%	18	9.18%	3	1.53%	196
ISS	58	78.38%	11	14.86%	5	6.76%	74
TS	18	60.00%	6	20.00%	6	20.00%	30
Total	251	83.67%	35	11.67%	14	4.67%	300

Table 10: Description of patients' adherence to treatment during one year.

Indication	Yes No.	Yes %	No No.	No %	Total
GHD	155	79.08%	41	20.92%	196
ISS	43	58.11%	31	41.89%	74
TS	18	60.00%	12	40.00%	30
Total	216	72.00%	84	28.00%	300

Table 10 presents patients' adherence to recombinant growth hormone therapy (rGHT) according to the different treatment indications. The table summarizes the level of treatment adherence across the diagnostic groups, providing an overview of patients' compliance with the prescribed rGHT regimen during the study period.

Table 11 presents the effects of age at treatment initiation and adherence to recombinant growth hormone therapy (rGHT) on height changes after one year of treatment among patients with growth hormone deficiency (GHD), idiopathic short stature (ISS), and Turner syndrome (TS). The table summarizes the results of the regression analysis, including the regression.

Coefficients and their statistical significance, to evaluate the influence of these factors on treatment outcomes.

Table 12 presents the effects of age at treatment initiation, initial diagnosis, and adherence to recombinant growth hormone therapy (rGHT) on height changes after one year of treatment in the overall study population. The table summarizes the results of the multiple regression analysis, evaluating the contribution of these variables to treatment outcomes and identifying the factors associated with height improvement following rGHT.

Table 11: The effect of age at initiation of treatment and adherence to treatment separately on height after 1 year for each indication of rGHT.

Indication	Factor	α	p-value (α)	β	p-value (β)
GHD	Age	6.719	0.000	-0.0208	0.629
	Adherence	1.687	0.000	2.679	< 0.001
ISS	Age	4.209	0.000	-0.0115	0.818
	Adherence	2.017	0.000	1.305	< 0.001
TS	Age	11.26	0.000	-0.485	0.002
	Adherence	0.56	0.587	3.111	< 0.001

Table 12: The effect of age at initiation of treatment, initial diagnosis, and adherence to treatment on height after 1 year of rGHT for the whole sample.

Factor	α	p-value (α)	β	p-value (β)
Age at initiation	6.238	< 0.001	-0.0392	0.309
Initial diagnosis	3.080	< 0.001	1.064	< 0.001
Adherence	1.220	0.002	2.661	< 0.001

5. DISCUSSION

The study demonstrated that recombinant growth hormone therapy (rGHT) is an effective treatment for children with short stature, although treatment response varied according to the underlying diagnosis. Growth hormone deficiency (GHD) was the most common indication for therapy, and these patients achieved the greatest improvements in height and weight after one

year of treatment. In contrast, patients with idiopathic short stature (ISS) and Turner syndrome (TS) showed more limited responses, indicating that treatment outcomes are strongly influenced by the underlying etiology.

In addition to improving physical growth, rGHT had a positive impact on psychosocial outcomes, particularly in children with GHD. However, improvements in mood, behavior, self-esteem, and social functioning were less evident in ISS and TS, suggesting that hormonal therapy alone may not fully address the psychological and social challenges associated with these conditions. Therefore, multidisciplinary care, including psychological support, may further enhance patient outcomes.

The therapy was generally well tolerated, with only a small proportion of patients experiencing mild adverse effects. Better treatment adherence and regular follow-up were associated with greater improvements in growth, emphasizing the importance of patient and family education throughout therapy.

Finally, treatment adherence and the initial diagnosis were the strongest predictors of height improvement after one year of rGHT. Although age at treatment initiation was not associated with better outcomes in the overall sample, earlier treatment appeared to provide greater benefit in patients with Turner syndrome. These findings highlight the importance of early diagnosis, individualized treatment, and high adherence to maximize the effectiveness of recombinant growth hormone therapy.

6. CONCLUSION AND RECOMMENDATIONS

Recombinant growth hormone therapy (rGHT) was effective and generally safe in children with short stature, with the greatest benefit observed in patients with growth hormone deficiency (GHD). Treatment response varied according to the underlying diagnosis, while adherence to therapy was the strongest predictor of height improvement. Early diagnosis, timely referral, regular follow-up, and a multidisciplinary approach are recommended to maximize treatment outcomes, particularly in underserved areas.

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