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Psychological Adaptation in Children with Idiopathic Short Stature Treated with Growth Hormone or Placebo

JUDITH L. ROSS, DAVID E. SANDBERG, SUSAN R. ROSE, ELLEN WERBER LESCHEK, JEFFREY BARON, JOHN J. CHIPMAN, FERNANDO G. CASSORLA, CHARMIAN A. QUIGLEY, BRENDA J. CROWE, KRISTEN ROBERTS, AND GORDON B. CUTLER, JR.

Department of Pediatrics (J.L.R.), Thomas Jefferson University, Philadelphia, Pennsylvania 19107; A. I. DuPont Hospital for Children (J.L.R.), Wilmington, Delaware 19899; Departments of Psychiatry and Pediatrics (D.E.S.), University at Buffalo, The State University of New York, Buffalo, New York 14222; Developmental Endocrinology Branch (E.W.L., J.B.), National Institute of Child Health and Human Development, National Institutes of Health, Bethesda, Maryland 20892; Department of Endocrinology (S.R.R.), Cincinnati Children's Hospital Medical Center and The University of Cincinnati, Cincinnati, Ohio 45229; Institute of Maternal and Child Research (F.G.C.), University of Chile, Santiago, Chile; and Eli Lilly and Co. (C.A.Q., J.J.C., B.J.C., G.B.C., K.R.), Indianapolis, Indiana 46285

The influence of short stature on psychological adaptation in childhood and adolescence is controversial. GH is currently used to treat children with idiopathic short stature (ISS, also known as non-GH-deficient short stature). This study represents the first double-blind, placebo-controlled trial of the effects of GH on the psychological adaptation of children and adolescents with ISS, treated with GH until adult height was attained.

Sixty-eight children (53 males, 15 females), 9–16 yr old, with marked ISS (measured height or predicted adult height −2.5 SD or less) received either GH 0.074 mg/kg or placebo sc three times per week until height velocity decreased to less than 1.5 cm/yr. Parents completed the Child Behavior Checklist (CBCL) and children the Self-Perception Profile (SPP) and Silhouette Apperception Technique at baseline and annually thereafter.

Baseline behavioral/emotional adjustment (CBCL) and self-concept (SPP) scores for children with ISS were within the normative range. The two study groups exhibited similar behavioral and self-concept profiles (CBCL) during the first 2 yr of the study. However, CBCL behavior problems (internalizing, externalizing, and total problems) appeared to decline, in yr 3 and 4, in the GH-treated group relative to the placebo-treated group. Group differences in CBCL competency domains and the SPP were not observed at any point during the study.

Short stature among children with ISS enrolled in this long-term, placebo-controlled study was not associated with problems in psychological adaptation or self-concept with the psychological instruments employed. GH treatment was associated with a trend toward improvement in problem behaviors, as measured by questionnaires (CBCL) completed by study participants' parents. It remains to be determined whether GH treatment significantly impacts adaptation, psychosocial function, or quality of life in children with ISS. (*J Clin Endocrinol Metab* 89: 4873–4878, 2004)

DECREASED CHILDHOOD GROWTH resulting in short stature can be caused by endocrine or chromosomal abnormalities, genetic defects in endochondral bone formation, malnutrition, chronic systemic disease, or psychosocial deprivation. However, in many children a specific etiology for the growth failure cannot be identified, a condition referred to as idiopathic short stature (ISS) or non-GH-deficient short stature. Growth failure in this condition can range from mild to severe (1–3). Most, but not all, nonrandomized long-term studies assessing long-term efficacy of GH therapy in increasing adult height suggest that GH therapy has a positive effect on the adult height of children without GH deficiency (1–4).

Anecdotally reported experiences associated with short stature include teasing, socialization according to height age rather than chronological age (*i.e.* juvenilization), and academic underachievement, according to clinic-based populations. Although studies have corroborated these clinical impressions (5–9), others have failed to demonstrate that such stressors translate into problems of daily psychosocial or educational functioning (10–13). It has been suggested that short-statured children employ a variety of coping techniques to adapt to the difficulties that their height imposes (14), a strategy that may result in positive psychological adaptation comparable to peers.

Short stature has been associated with negative stereotypes (15). It is possibly in reaction to these factors that many with short stature be taller, even if they are not exhibiting major problems in psychosocial adaptation. According to one community-based study conducted in the United Kingdom, only 12% of short, healthy children (less than third percentile) were satisfied with their height, compared with 47% of the comparison sample (10th to 90th percentiles) (16, 17).

With the availability of biosynthetic GH, opportunities for treatment have been extended to multiple patient groups with short stature who are not GH deficient including those with chronic renal insufficiency, Turner syndrome, children born small for gestational age, and most recently children

Abbreviations: CBCL, Child Behavior Checklist; ISS, idiopathic short stature; SAT, Silhouette Apperception Technique; SDS, SD score; SPP, Self-Perception Profile.

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with ISS (2). One possible justification for the treatment of children with ISS is the belief that short stature is associated with psychological disadvantages and that hormonally induced increases in height may improve the day-to-day lives of affected individuals.

We report here the psychological findings from the first randomized, double-blind, placebo-controlled trial of GH therapy in peripubertal children with ISS. Adult height was significantly greater in the GH-treated group than in the placebo-treated group and is reported elsewhere (18). This study examines the psychosocial adaptation and self-concept of children with ISS before initiation of GH therapy and evaluates prospectively whether GH treatment affects these same outcome variables.

Subjects and Methods

Subjects

Inclusion criteria for study participation were: 1) age 10–16 (boys) or 9–15 yr (girls), 2) bone age 13 or less (boys) or 11 yr or less (girls), 3) testicular volume 10 ml or less (boys) or Tanner stage breast development 2 or less (girls), 4) marked, proportionate short stature, and 5) peak stimulated GH greater than 7 μg/liter (19). Marked short stature (within the 12 months before study initiation) was defined by an absolute or predicted height −2.5 SD or less . Exclusion criteria were chronic illness; a known genetic syndrome; previous treatment with GH, estrogen, or androgen; or current treatment with other drugs likely to affect growth, including methylphenidate or similar stimulants. Seventy-one patients were enrolled in this study between 1988 and 1999. Three withdrew before receiving the study drug and were not included in the data analyses. Fifty-nine of the 71 enrolled patients participated in the psychosocial evaluations.

Protocol

The protocol was approved by the Institutional Review Board of the NICHD and Thomas Jefferson University. Informed assent/consent was obtained from the subject and a parent.

Patients were randomly assigned to receive three equally divided doses per week of either recombinant human GH (Humatrope, Eli Lilly and Co., Indianapolis, IN) 0.22 mg/kg·wk or placebo by sc injection. This dose and frequency represented regimens commonly used at the time of study design (1987). While receiving the study drug, subjects were evaluated every 6 months for efficacy and safety. The study drug was continued until the growth rate decreased less than 1.5 cm/yr.

In June 2000, an independent Data and Safety Monitoring Board recommended study discontinuation and data analysis because the slow accrual of additional data did not warrant continuation of the long-term placebo injection control group.

Psychological test procedures

The primary care-taking parent of each child completed a Child Behavior Checklist (CBCL) and the child completed the Self-Perception Profile (SPP) and Silhouette Apperception Test (SAT) at baseline and yearly, during the study.

The CBCL is a standardized parent-report measure of academic and social competencies as well as behavioral and emotional problems in children and adolescents aged 4 to 18 yr (20). The CBCL assesses three *a priori* constructed competency domains (activities, social, and school) and eight factor-analytically derived narrow-band problem behavior areas. The behavior problems scales are further classified into two broad-band problem domains (internalizing and externalizing). This broad-band classification of problems reflects the distinction between fearful, inhibited, and overcontrolled behavior (*i.e.* internalizing) and aggressive, antisocial, and undercontrolled behavior (*i.e.* externalizing). Reliability and validity for the CBCL is well established, and the measure has been extensively validated and used internationally for over 30 yr (21–24). Results are reported as T-scores (mean = 50, SD = 10).

The SPP (25) assesses domain-specific judgments by children and adolescents of their personal competence as well as a global perception of their worth or esteem as a person. Items are organized in the following six scales: 1) social acceptance, 2) scholastic competence, 3) athletic competence, 4) physical appearance, 5) behavioral conduct, and 6) global self-worth. The assessment of perceived social competence and personal esteem adds information that cannot be gleaned from informants other than the child. The physical appearance scale assesses the individual's satisfaction with face and body appearance (but not specifically height). Higher scores reflect more positive self-concepts. Normative data are available from 2300 third- to 12th-grade children. As in the case of the CBCL, the SPP has been used in multiple studies, including investigations of the psychosocial consequences of short stature (26, 27). Results are reported as T-scores (mean = 50, SD = 10), derived from published normative values (28).

The SAT (29) has been used to assess the accuracy of self-perceptions of height in studies of short children (30). The SAT assesses children's and adolescents' perception of their own body size, compared with that of their age-related peers. The child is asked to match his or her present height to one of five silhouettes of varying size, drawn proportionately to represent the third, 25th, 50th, 75th, and 97th percentiles and appearing on the form in a fixed random order to minimize response bias. The respective height ranges for each silhouette are: less than first to 14th percentile (silhouette 1); 15th to 37th percentile (silhouette 2); 38th to 62nd percentile (silhouette 3); 63rd to 86th percentile (silhouette 4); and 87th to more than 99th percentile (silhouette 5)

Statistical analysis

Results are expressed as mean ± SD; *t* tests, comparing the GH and placebo-treated groups, were performed year by year on actual scores from the CBCL, SPP, and SAT. Change from baseline T-scores for yr 1–4 were also analyzed using *t*-tests for the CBCL results. In addition, Pearson correlation coefficients were calculated comparing change from baseline in height SD score (SDS) with the change from baseline in scores for the CBCL as well as the actual values at the visit. Wilcoxon signed ranks tests were performed to test SAT change-from-baseline scores at yr 1–4. Wilcoxon rank sum tests were used to compare the GH and placebo-treated groups for the year-by-year SAT scores. The statistical analyses have not been adjusted for multiple comparisons. Significance was set at a two-sided level of 0.05. Gender differences were not examined because of the relatively smaller number of females, compared with males.

Results

Baseline evaluation

Study participants and parents completed questionnaires at baseline and after completing 1, 2, 3, and 4 yr of treatment with GH or placebo. At study entry, the mean age of participants, all of whom were prepubertal or peripubertal, was 12.4 ± 1.5 yr. Most (78%) of the participants were male (Table 1).

Mean baseline values for the parent-reported CBCL fell within one SD of norms for the general population (Table 2). The same was true for the patient-reported SPP (Table 3). Furthermore, the GH- and placebo-treated groups had similar scores on the CBCL and SPP at baseline. Pearson correlations, comparing baseline height SDS values to the indi-

TABLE 1. Baseline characteristics of the enrolled study population (mean ± SD)

	GH	Placebo
N	37 (29 m, 8 f)	31 (24 m, 7 f)
Chronological age (yr)	12.5 ± 1.6	12.2 ± 1.4
Bone age (yr)	10.4 ± 1.9	10.3 ± 1.7
Height SDS	−2.8 ± 0.5	−2.8 ± 0.5

m, Male; f, female.

TABLE 2. Baseline values for the parent report CBCL (T-scores, mean ± SD)

	GH (n = 33)	Placebo (n = 26)
Social competency[a]		
Activities	49 ± 7	49 ± 5
Social	47 ± 8	47 ± 9
School	49 ± 7	47 ± 9
Behavior problems[b]		
Total problems	51 ± 10	51 ± 11
Broad-band problem scales		
Internalizing	52 ± 12	51 ± 11
Externalizing	49 ± 9	49 ± 10
Narrow-band problem scales		
Withdrawn	53 ± 6	53 ± 6
Somatic	57 ± 8	57 ± 8
Anxiety/depression	56 ± 9	54 ± 5
Social problems	56 ± 7	57 ± 7
Thought problems	54 ± 7	54 ± 6
Attention	54 ± 6	57 ± 7
Delinquent	53 ± 5	54 ± 6
Aggressive	53 ± 5	53 ± 7

T-scores: mean = 50; 1 SD = 10.
[a] Higher score indicates greater competence.
[b] Higher score indicates greater behavior problem.

TABLE 3. Baseline values for SPP[a] (T-scores, mean ± SD)[b]

	GH (n = 32)	Placebo (n = 27)
Scholastic competence	53 ± 12	53 ± 8
Social acceptance	53 ± 10	48 ± 10
Athletic competence	51 ± 11	49 ± 10
Physical appearance	48 ± 10	50 ± 7
Behavior conduct	50 ± 11	47 ± 12
Global self-worth	54 ± 10	51 ± 7

[a] Higher score indicates greater self-esteem.
[b] T-scores: mean = 50; 1 SD = 10.

vidual baseline CBCL variables were significant for one CBCL summary scale: internalizing ($r = 0.31$, $P = 0.02$, Fig. 1).

The mean ratings for the SAT were similar for the GH- and placebo-treated groups, (1.8 ± 0.7 and 2.0 ± 0.8 at baseline, $P = 0.32$), indicating that on average, participants viewed themselves as having heights between the third and 25th percentile (silhouettes 1 and 2, respectively). The measured height of participants at baseline was, on average, below the first percentile (<2.25 SD).

Psychosocial adaptation across years of treatment

Numbers of patients participating at each time point and mean scores for change from baseline on the CBCL are provided in Table 4. The number of study participants decreased each year due to study drop-outs, primarily related to patient decision resulting from the inconvenience of a long-term, placebo-controlled study as well as missing data. The drop-outs were similar to the study completers in terms of baseline characteristics, and the drop out rate was similar for the GH and placebo groups. By the third year of the study, participants were, on average, 15.2 yr old, and well into adolescence. By the fourth year of the study, the number of remaining participants was quite small.

Deviations from baseline scores for the CBCL total problems and internalizing and externalizing scales are illustrated across the 4 yr of treatment in Figs. 2 through 4, respectively. Statistically significant differences between the groups were not detected at yr 1 or 2 on any of the CBCL summary scales. By yr 3 and 4, however, the placebo group exhibited increased problems, whereas the GH group showed a relative decline. These differences achieved statistical significance on all three CBCL summary scales by treatment yr 4. By the fourth year, the mean scaled scores had increased by approximately 1 SD in the placebo group, suggesting a deterioration in behavior, whereas mean scaled scores decreased by about 1 SD in the GH group, indicating relative improvement (Figs. 3 and 4). The mean scores, despite these changes, remained within the normal range. Also, there were no differences in CBCL social competency scores at any point in the study.

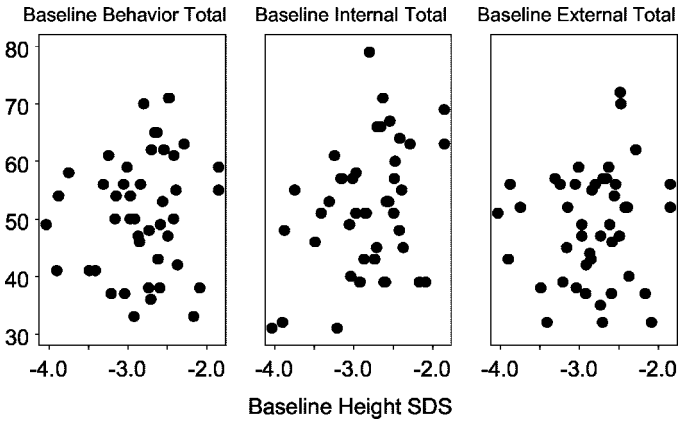

FIG. 1. Plot of baseline height SDS *vs.* baseline CBCL problem behavior total, internalizing, and externalizing scales.

On the SPP, differences between the GH and placebo-treated groups did not achieve statistical significance at baseline or at any follow-up point (data not shown). The SAT scores were similar in the GH and placebo groups at yr 1–4 (Fig. 5). The GH and placebo groups appeared to diverge in the fourth year, with only the GH group perceiving themselves as getting taller; however, this divergence did not attain statistical significance.

Finally, no systematic significant relationship was observed between attained height SDS, or the change in height SDS scores, and annual changes in score for the CBCL variables T-scores.

Discussion

In the present investigation of self-image and behavior in children with ISS, baseline and GH treatment-associated changes were examined. This study was the first to employ a randomized, double-blind, placebo-controlled design, which avoids the shortcomings of designs with historical or nonrandomized controls.

The baseline parent-reported behavioral adjustment and self-concept of children (9–16 yr) in the present study were comparable with those of the general population. Notably, the participants in this particular study were highly self-selected subjects with respect to their willingness to participate in a long-term, placebo-controlled trial. Similarly, there was no evidence from the CBCL or SPP to support the hy-

TABLE 4. CBCL (T-score) change (study year value minus baseline) at yr 1, 2, 3, and 4 (mean ± SD)

	GH				Placebo			
	yr 1 (n = 17)	yr 2 (n = 23)	yr 3 (n = 12)	yr 4 (n = 9)	yr 1 (n = 9)	yr 2 (n = 19)	yr 3 (n = 9)	yr 4 (n = 3)
Social competencies[a]								
Activities	−3.2 ± 6.6	−3.6 ± 7.2	−2.2 ± 7.4	−4.6 ± 7.5	−2.8 ± 7.5	−3.5 ± 8.3	−5.8 ± 10.9	−4.7 ± 7.1
Social	1.1 ± 7.8	0.3 ± 9.9	1.8 ± 11.6	6.5 ± 11.7	−4.5 ± 11.5	−3.1 ± 9.3	−1.7 ± 8.4	7.0 ± 6.6
School	−1.7 ± 5.5	−0.9 ± 6.3	0.9 ± 6.8	−2.6 ± 7.8	0.7 ± 3.8	0.4 ± 3.3	−0.7 ± 4.4	1.7 ± 2.9
Behavior problems[b]								
Total	0.1 ± 6.5	−0.7 ± 6.9	−5.2 ± 8.8	−7.4 ± 9.5	1.4 ± 12.7	−3.8 ± 12.2	2.4 ± 9.0	8.7 ± 8.5
Internalizing	−1.8 ± 8.7	−2.5 ± 7.9	−5.4 ± 9.0	−5.3 ± 7.5	1.8 ± 12.2	−3.5 ± 11.5	1.7 ± 9.2	7.3 ± 12.1
Externalizing	0.5 ± 7.2	0.7 ± 6.3	−1.1 ± 6.5	−4.8 ± 7.8	1.9 ± 11.9	−0.6 ± 10.6	5.8 ± 8.0	9.3 ± 4.7

[a] Positive score indicates improvement; negative score indicates worsening.
[b] Positive score indicates worsening; negative score indicates improvement.

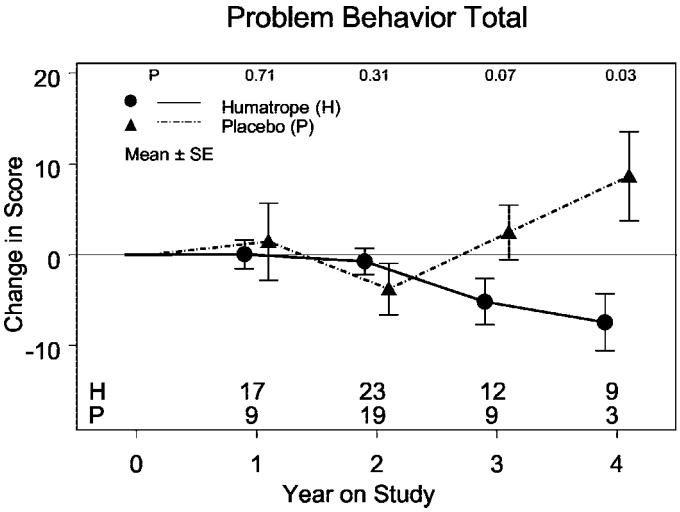

FIG. 2. Change in T score for the CBCL total problem behavior scale.

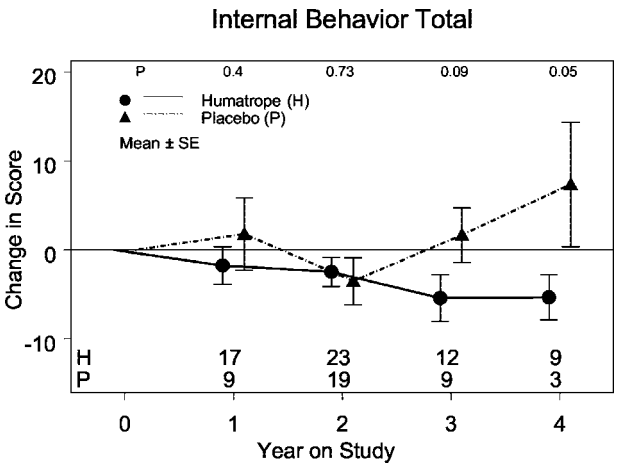

FIG. 3. Change in T score for the CBCL internal behavior scale.

pothesis that short stature, in this referral population, is associated with a poor self-image or increased behavior or emotional problems at the time of referral. This general finding has been observed in some studies (10–13) but not others (5–8).

According to the SAT results, the ISS study participants tended to perceive themselves, on average, as somewhat taller then they were, in agreement with another study (30). We cannot discern whether they wish they were taller, had

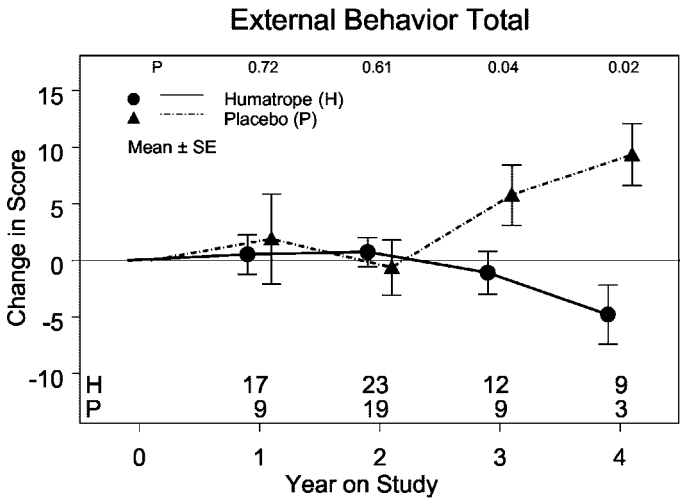

FIG. 4. Change in T score for the CBCL external behavior scale.

image distortion, or did not fully understand the task. Second, we could not discern whether this perception represented psychological adaptation or a defense mechanism.

Treatment-related changes in self-concept (SPP) were not observed over the 4 yr of GH therapy. However, parents of GH-treated participants noted a decline in behavior problems (CBCL) during years 3 and 4 of intervention in relation to both their baseline scores and the placebo group. This finding was statistically significant at yr 3 of study for the externalizing behavior scale. No relationship between self-image and growth rate or height was observed. The GH-treated study participants in the present study were, on average, 0.5 SDS (3.7 cm) taller than the placebo-treated group, on achieving adult height (18). Thus, the present findings provide reassurance that treatment of short stature with GH is not associated with deterioration in psychological functioning, refuting the hypothesis that providing medical intervention to short children exacerbates feelings of being different (7).

Certain methodological limitations may have limited the chance of detecting treatment-related changes in self-concept when it is present (type II error), or alternatively, may have resulted in finding significant associations when none is present (type I error). These errors may be related to the small sample size, the large number of tests performed, subject attrition rate, and missing questionnaire data. Also, the study instruments may not have been optimally sensitive for as-

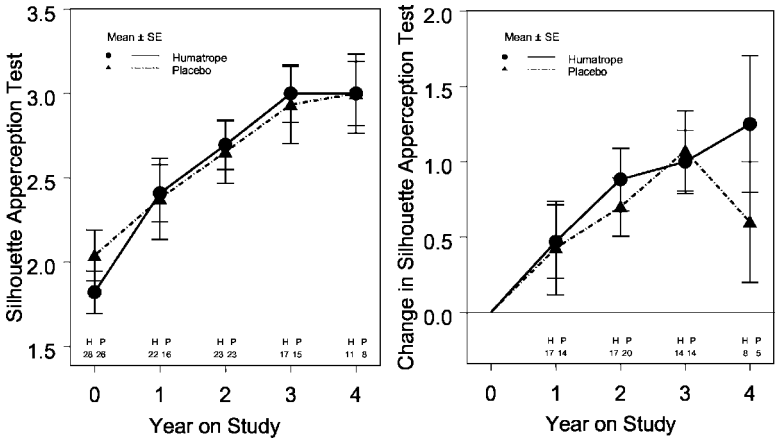

FIG. 5. Baseline SAT scores and change from baseline.

sessing self-concept in this population. Last, the dose, frequency of injections, and duration of treatment did not represent current GH treatment regimens. A more optimal GH regimen started at a younger age may have produced better height gain and thus greater psychological improvement. A ceiling effect, because the study participants were already functioning within the normal range at baseline, may have limited opportunity to observe improvement in psychosocial functioning and self-concept. Alternatively, mobilization of coping mechanisms may potentially blur outcome measures, as cogently developed by Noeker and Haverkamp (14). Last, the multiple comparisons increase the likelihood of finding spurious associations.

Earlier studies have assessed the potential benefits of GH therapy on psychosocial adaptation and self-image among individuals with idiopathic short stature (31, 32). Two previous studies (31, 33), which employed a randomized, untreated control design, observed no differences in quality of life between GH-treated and untreated groups; however, the GH-treated children reported improved body satisfaction (33). The children in both studies were on average considerably younger (age 4–10 yr at start of treatment *vs.* 9–15 yr in the current study) and received GH for a shorter treatment interval (2 *vs.* 3.5 ± 1.8 yr in this study) (31). Other studies of the psychological effects of GH treatment in short children employed either nonrandomized control groups (26, 34) or no control groups (32, 35, 36). By contrast, the randomized, placebo-controlled design of our study avoided these shortcomings.

Mild short stature appears to cause only mild psychological consequences and is usually not treated medically. For more severe short stature, the psychological consequences and the value of treatment are likely to remain more controversial due to numerous methodological issues. These issues include the difficulty in conducting long-term, placebo-controlled studies; the question of the ascertainment of patients selected for such studies; and the question of whether the available psychological instruments are sensitive to the specific domains that may be affected in short children. Ultimately, the benefits of treating an individual child with GH to achieve taller adult height will depend to some extent on the importance ascribed to height by the patient, the family, and the clinician. In this context, the clinical assessment of a short child should include the psychosocial context and the identification of adaptive coping strategies.

In summary, the baseline psychological adaptation of children with short stature who participated in this randomized trial fell within the range observed in the general population. Furthermore, the results showed trends, after 3–4 yr, of reduced externalizing behavior problems, compared with placebo. The data do not support the use of GH treatment for idiopathic short stature to improve psychological dysfunction. Indeed, whereas GH treatment can be conclusively shown to improve both short-term and long-term height in a number of conditions associated with growth failure and short stature, it remains to be determined whether such treatment significantly impacts adaptation, psychosocial function, or quality of life in any growth disorder.

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Address all correspondence and requests for reprints to: Judith L. Ross, M.D., Thomas Jefferson University, Department of Pediatrics, 1025 Walnut Street, Philadelphia, Pennsylvania 19107. E-mail: judith.ross@mail.tju.edu.

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