Testing the performance of a preexisting growth prediction model in a cohort of prepubertal patients born small for gestational age (SGA) receiving growth hormone treatment in PATRO children

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INTRODUCTION

Growth hormone (GH) treatment of short children born SGA and its effects on growth varies greatly between treated individuals. In the present study we tested the performance of a preexisting growth prediction model to estimate first-year height gain in a german cohort of prepubertal children born SGA treated with GH (Omnitrope®).

PATIENTS and METHODS

190 treatment-naïve prepubertal children born SGA (72 girls, birth weight and/or birth length < - 2.0 SD) were enrolled within the international post authorization safety study PATRO children®. The model was validated by comparing predicted and observed height gain in the first year of treatment with Omnitrope®.

Growth prediction model *

Height gain in the 1st year of GH treatment (cm/year) =

8.0 +

− 0.31 × Age at start of therapy (years)

0.30 × Body weight at start (SDS)

8.07 × GH dose (mg/kg×day)

0.11 × Midparental height (SDS)

* Ranke et al.; JCE&M 2003 pp 125-131

RESULTS

Baseline characteristics at start of GH treatment are given in *table 1*. Results of growth prediction and the outcome measures of height gain after 1 year of GH treatment as well as the index of responsiveness are given in *table 2*.
Mean predicted and observed 1-year HV were similar and the mean index of responsiveness was close to zero.

Parameter	Mean	SD	Min	Median	Max
Age (years)	6.6	2.1	4.0	6.0	11.8
Height (SDS)	−3.1	0.49	−5.6	−2.9	−2.2
BMI (SDS)	−0.84	1.4	−4.8	−0.76	4.3
Midparental height (SDS)	−0.72	1.08	−3.66	−0.71	1.98
IGF-I (SDS)	−0.96	1.18	−2.81	−1.0	3.18
GH dose (mg/kg·day)	0.032	0.006	0.014	0.033	0.060

Table 1: Baseline characteristics of the treatment-naïve prepubertal SGA cohort.

RESULTS cont.

Parameter	Mean	SD	Min	Median	Max
1st-year predicted height gain (cm)	8.61	0.73	5.86	8.78	14.2
1st-year observed height gain (cm)	8.56	1.54	4.8	8.80	10.7
1st-year Δ height SDS	0.73	0.30	−0.13	0.74	1.80
1st-year height velocity SDS	3.72	2.14	−1.80	3.65	11.6
Index of Responsiveness	−0.024	1.09	−2.93	−0.02	4.13

Table 2: Growth prediction and outcome measures of height gain after 12 months of GH treatment.

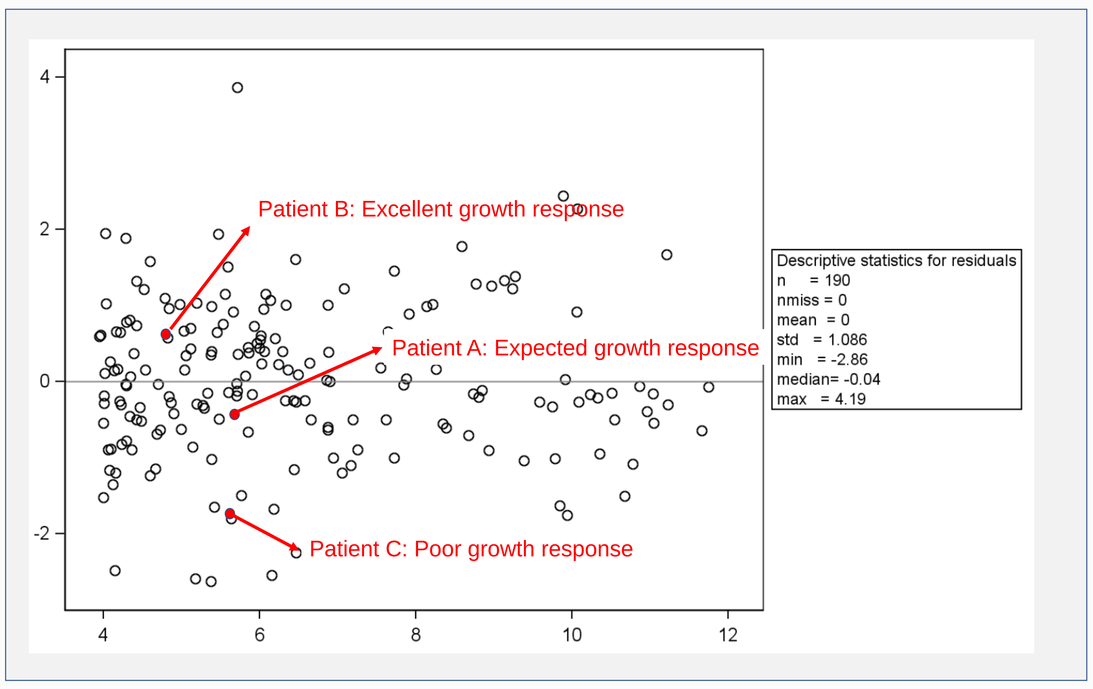

Table 3: Growth prediction and outcome measures after 12 months of GH treatment.

Parameter	Patient A Expected growth response	Patient B Excellent growth response	Patient C Poor growth response
Gender	Female	Female	Male
Age	5.6	4.5	5.5
Height SDS	- 3.45	- 3.83	- 3.68
Difference to target height (SDS)	- 2.60	- 2.74	- 2.70
Birth weight (SDS)	- 2.12	- 3.14	- 2.95
Body weight at start (SDS)	- 1.29	- 2.16	- 2.52
GH dose at start (mg/kg x d)	0.036	0.019	0.033
Predicted 1st year height gain (cm/year)	9.60	8.40	8.63
Observed 1st year height gain (cm/year)	9.53	11.0	6.0
Observed 1st year height gain (SDS)	0.995	1.37	0.18
Index of Responsiveness	0.054	1.98	- 2.02

Table 3: Case series of three young SGA patients treated with GH. Growth response to GH treatment was very different in these patients due to different responsiveness to GH, reflected by the *Index of Responsiveness*.

CONCLUSIONS

Our results indicate accurate performance of the growth prediction model in prepubertal patients born SGA treated with the biosimilar Omnitrope®. It may therefore be used to monitor growth response and to individualize GH therapy in these children.