DETERMINING FACTORS OF A GOOD RESPONSE TO TREATMENT WITH GROWTH HORMONE FOR THE FIRST 2 YEARS

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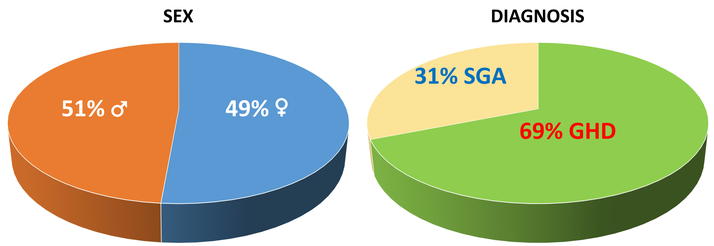
OBJECTIVES

- To establish the main factors on which a good response to GH treatment depends during the first 2 years of treatment.
- To study the optimum adherence values during the first and second year of treatment.
- To determine if the Index of responsiveness (IoR) can help to differentiate the good from the bad responders.

MATERIAL AND METHODS

- This is a non-interventional, retrospective observational study, by reviewing medical records of patients undergoing growth hormone treatment for at least 2 years due to growth hormone deficiency (GHD) or Small for gestational age (SGA).
- Demographic data (sex, place of residence, parental studies), diagnosis (GHD, SGA), treatment characteristics, anthropometric data (perinatal, familial and evolutionary auxology during the year prior to the start of treatment and 2 years later), laboratory parameters (IGF-1, IGF-BP3 levels, maximum GH peak after stimuli) and treatment adherence data (percentage of doses correctly applied in each period of time) were reviewed. Patients received treatment with Saizen®, allowing to assess adherence to treatment through the EasyPod Connect platform. In addition, the presence of adverse events has been studied.
- IoR in the first and second year was calculated.
- Statistical significance has been considered when p<0.05. Multivariate models have been made to construct response prediction models using as dependent variables height velocity (HV) and height gain in SDS.

RESULTS



N=110

Table 1. Two years evolution data

	X	DS
Age at start r-GH (years)	8,49	3,82
r-GH dose (mg/kg/day)	0,03	0,01
Height at start r-GH (SDS)	-2,65	0,52
Height velocity (cm/year) preGH	4,55	1,11
Height velocity (SDS) preGH	-2,04	0,95
Height gain (SDS) preGH	-0,23	0,30
Age at year 1 (years)	9,48	3,81
r-GH dose (mg/kg/day)	0,03	0,00
Height at year 1 (SDS)	-2,09	0,57
Height velocity (cm/year)	8,60	1,72
Height velocity (SDS)	2,38	1,73
Height gain (SDS)	0,58	0,33
Adherence 1 year (%)	95,64	5,73
IoR1	-0,08	1,31
Age at year 2 (years)	10,52	3,82
r-GH dose (mg/kg/day)	0,03	0,01
Height at year 2(SDS)	-1,66	0,61
Height velocity (cm/year)	7,42	1,64
Height velocity (SDS)	1,90	1,83
Height gain (SDS)	0,43	0,32
Adherence 2 year (%)	93,98	7,61
IoR2	0,20	1,23

Table 2. Factors of good response year 1.

		Δ height >0.3DS		Δ height >0.5DS		HV >1 DS		Δ HV > 3 cm/year	
		YES N=95	NO N=15	YES N=59	NO N=51	YES N=90	NO N=20	YES N=78	NO N=32
Adherence %	X	95.92	93.87	95.86	95.37	96.03	93.85	95.15	94.32
	DS	5.6	6.09	6.25	5.12	5.40	6.92	4.96	7.23
		n.s.		*n.s.*		*n.s.*		*n.s.*	
Height SDS	X	-2.02	-2.47	-1.89	-2.31	-2.01	-2.42	-1.93	-2.45
	DS	0.56	0.54	0.55	0.52	0.54	0.61	0.50	0.57
		P=0.005		*P<0.01*		*P=0.003*		*P<0.01*	
HV SDS	X	2.61	0.93	2.97	1.69	2.83	0.34	2.87	1.17
	DS	1.73	0.77	1.80	1.38	1.56	0.69	1.71	1.06
		P<0.01		*P<0.01*		*P<0.01*		*P<0.01*	
Δ height SDS	X	0.65	0.14	0.79	0.32	0.63	0.35	0.63	0.44
	DS	0.29	0.14	0.28	0.15	0.32	0.26	0.34	0.24
		P<0.01		*P<0.01*		*P<0.01*		*P=0.005*	
HV1-HV0	X	4.29	2.49	4.49	2.52	4.40	2.45	4.99	1.73
	DS	1.91	1.99	1.94	1.99	1.87	1.91	1.49	0.97
		P=0.001		*P=0.011*		*P<0.01*		*P<0.01*	
IoR1	X	0.04	-0.89	0.24	-0.45	0.15	-1.13	0.42	-1.31
	DS	1.30	1.09	1.24	1.24	1.22	1.16	1.13	0.78
		P=0.009		*P=0.005*		*P<0.01*		*P<0.01*	

Table 3. Factors of good response year 2.

	IoR2	
	r	p
Height SDS	0,201	0,035
Height velocity SDS	0,401	0,000

	Adherence 2 year	
	r	P
HV1-HV0	0,201	0,035
Adherence year 2	0,836	0,000
IoR2	0,298	0,002

An adherence > 90% during the first year have more frequently a HV> 1SDS (p = 0.025) and therefore, higher height SDS (p = 0.003) and height gain SDS (p = 0.000) the first year.

There is a higher HV at 2 years in cm / year in those with an adherence above 85% vs. those with <85% (7.6 ± 1.61 vs 6.1 ± 1.34 cm / year, p = 0.001).

CONCLUSIONS

- Adherence is a determining parameter in the response to treatment with GH.
- A value> 90% is estimated as optimal for a better response the first year of treatment, and > 85% the second year.
- The percentage of adherence is higher in those patients with greater growth restriction at the beginning of treatment and remains high in those with higher HV.
- IoR both in the first and in the second year of treatment, allows to know the patients who will be good responders to the treatment with GH.

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