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ORIGINAL ARTICLE

Study on growth hormone treatment in small for gestational age children☆

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KEYWORDS
Small for gestational age;
Human growth hormone;
Short stature

Abstract
Objective: To analyse the effectiveness of growth hormone (GH) therapy in short-stature children born small for gestational age (SGA) without catch-up growth (height at the beginning of treatment < −2.5 SDS), in Valencia (Spain), between 01/01/2003 and 12/31/2013; and to compare our findings with previously published data.
Materials and methods: Anthropometric data from the SGA children were obtained from the database of the ''Ministry of Health of Valencia''. These data were retrospectively reviewed.
Results: A total of 115 SGA children, with a mean age of 8.10 ± 2.75 years and height of −3.14 ± 0.59 SDS started treatment (dose: 0.035 ± 0.004 mg/kg/day) between January 1st, 2003 and March 31st, 2013. After 2 years of therapy (n = 115, age: 10.50 ± 2.72 years) the height SDS was −2.11 ± 0.66; and after 4 years (n = 96, age: 12.65 ± 2.46 years) of −1.76 ± 0.75 SDS. This latest improvement in stature matches ages at which the growth spurt usually occurs. Only 35 out of 115 children reached adult height, although impaired (−2.22 ± 0.86 SDS), and failed to achieve their target height (−1.72 ± 0.75 SDS). However, this sub-group grew to near the height of the shorter parent (−1.95 ± 1.28 SDS), and 42.9% of these 35 cases increased their stature by more than 1 SDS.
Conclusions: The studied sample did not achieve satisfactory growth results, as in other published series. Our findings might be improved by starting treatment earlier, and with doses individualised according to patient characteristics.
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PALABRAS CLAVE
Pequeño para la edad gestacional;
Hormona de crecimiento humana;
Talla baja

Estudio valenciano sobre tratamiento con hormona de crecimiento en pequeños para la edad gestacional

Resumen
Objetivo: Valorar la efectividad del tratamiento con hormona de crecimiento (GH) en niños pequeños para la edad gestacional (PEG) sin crecimiento recuperador (talla al iniciar la terapia < −2,5 DE), en la Comunidad Valenciana, entre el 01/01/2003 y el 31/12/2013, y comparar los resultados con los ya publicados.
Material y métodos: Los datos antropométricos de los PEG que constituyeron la muestra de estudio se recogieron retrospectivamente de los documentos de solicitud de tratamiento existentes en la Consejería de Sanidad de Valencia.
Resultados: Un total de 115 sujetos comenzaron a tratarse entre el 01/01/2003 y el 31/12/2013, con dosis de GH de 0,035 ± 0,004 mg/kg/día, a una edad de 8,10 ± 2,75 años y con una talla de −3,14 ± 0,59 DE. Talla alcanzada tras 2 años de terapia (n = 115, edad: 10,50 ± 2,72 años): −2,11 ± 0,66 DE; y tras 4 años (n = 96, edad: 12,65 ± 2,46 años): −1,76 ± 0,75 DE. Esta última mejoría de talla coincide con edades a las que suele producirse el estirón puberal. Solo 35 de los 115 niños finalizaron el crecimiento, en el periodo de estudio, a una edad de 16,22 ± 1,19 años. Este subgrupo no consiguió normalizar la talla adulta (−2,22 ± 0,86 DE), ni alcanzar su talla diana (−1,72 ± 0,75 DE); no obstante, hubo una buena aproximación a la talla del progenitor más bajo (−1,95 ± 1,28 DE). El 42,9% de estos 35 casos experimentaron un incremento de estatura superior a 1 DE.
Conclusiones: La muestra estudiada no obtiene una respuesta de crecimiento tan satisfactoria como las de otras series publicadas. Probablemente, estos resultados mejorarían iniciando el tratamiento más precozmente, e individualizando las dosis según las características del paciente.
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Introduction

Small for gestational age (SGA) refers to newborns whose birth weight or length are 2 or more standard deviations (SDs) below the mean for their sex and gestational age in the reference population.[1] This results from abnormalities in intrauterine growth, whose cause is unknown in 40% of cases.[2]

Approximately 90% of these children exhibit spontaneous catch-up growth in the first two years of life, although this may be delayed until age 3–4 years in children born preterm.[1] This catch-up growth does not occur in the remaining 10%, in most cases for unknown reasons.[3,4] Some of the possible causes that have been proposed include a decreased cell mass at the time of birth and alterations of endocrine-metabolic pathways involved in postnatal growth, especially in the GH-IGF-1 axis. However, growth hormone stimulation tests show normal or even elevated levels of growth hormone (GH) in most SGA children,[5] which suggests some degree of peripheral resistance to GH activity or a reduced biological activity of GH.

Job and colleagues were the first to use recombinant human growth hormone (rhGH) for the treatment of delayed postnatal growth seen in some children born SGA,[6,7] and set the foundations for subsequent research, the results of which suggests that rhGH is a safe and effective treatment to partially reduce stature deficits in the adult height of individuals born SGA. However, the response to treatment varies widely between studies, which may be related to the diverse aetiology of SGA.[8–11]

The use of this hormone for the treatment of short children born SGA was authorised by the Food and Drug Administration (FDA) in July 2001 and by the European Agency for the Evaluation of Medicinal Products (EMA) in June 2003.[1] The Spanish Agency of Medicines and Health Care Products (Agencia Española del Medicamento y Productos Sanitarios [AEMPS]) follows the criteria set by the EMA.

The dosage of rhGH recommended for children born SGA is higher than the one in children with GH deficiency, and ranges between 0.035 and 0.067 mg/kg/day.[1] The reason for this is that, as noted above, SGA patients exhibit a degree of peripheral resistance to GH activity rather than decreased GH release.

No studies have been conducted on the effectiveness of treatment in individuals born SGA in the Autonomous Community of Valencia since this indication for rhGH was approved. In this article, we present the growth outcomes in a sample of children treated over a 10-year period.

Objectives

(a) To assess the effectiveness of growth hormone in children born SGA in our area, between January 01, 2003 and December 31, 2013, based on the proportion of these patients that reached their target height by the end of treatment, or the corresponding growth trajectory if treatment was not completed.

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