Prevalence of children born small for gestational age P1-360 (SGA) with short stature who qualify for growth hormone treatment: a preliminary population-based study

Tamaro Gianluca¹, Pizzul Maria Grazia², Gaeta Giuliana², Servello Raffaella², Trevisan Marina², Böhm Patricia², Materassi Paola Manera Ada², Macaluso Anna², Valentini Denis¹, Pellegrin Maria Chiara³, Tornese Gianluca³

¹ University of Trieste, Trieste, Italy - ² Primary care pediatrician
³ Institute for Maternal and Child Health – IRCCS Burlo Garofolo, Trieste, Italy

gianluca.tornese@burlo.trieste.it

Recombinant human growth hormone (rhGH) is an approved and effective treatment for short children born small for gestational age (SGA). This treatment was approved in 2003 from the European EMEA (European Agency for the Evaluation of Medicinal Products) and in 2009 by the Italian Medicine Agency (AIFA) for the treatment of children with short stature born small for gestational age (SGA) and is then reimbursed by the Italian National Health System (Servizio Sanitario Nazionale – SSN) according to the Note for the use of drugs #39. According to the latest version (2014) of the Note #39 of AIFA, to access treatment with rhGH in individuals born SGA it is necessary to meet all the following criteria:



- Birth weight (BW) or birth length (BL) ≤ 2 SDS for sex and gestational age (GA) according to Bertino charts
- Age \geq 4 years
- Height ≤ 2.5 SDS
- Growth velocity < 50° percentile.

So far no study evaluated the prevalence of SGA children with short stature who qualify for rhGH treatment in Europe.

To investigate in an italian population the prevalence of:

- SGA
- Short stature in children born SGA
- SGA children who qualify for rhGH treatment at 4 years of age

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Preliminary population-based study on 7 out of 20 primary care pediatricians' databases in Trieste, Italy. Data on 3.769 children born between 2004 and 2014 and who had 4 years of follow up (over 20.120) were collected. BW and BL SDS for sex, GA and birth order were calculated according to Bertino Italian charts (<u>www.inescharts.it</u>). SGA was defined as

BW and/or BL ≤ - 2 SDS. Data on height and weight were collected at the closest visit to 1, 2, 3, 4 years of age and SDS were calculated (<u>www.weboriented.it/ghc3/</u>). Short stature was defined as height ≤ - 2 SDS according to WHO charts for children < 5 years. Short children born SGA who qualify for rhGH treatment were identified as for fulfilling all the aforementioned criteria.

Full data at birth were available for **3.250** children. The <u>prevalence of SGA</u> was **3.6%** (0.8% SGA for weight, 2.2% SGA for lenght, 0.6% SGA for both weight and lenght). The <u>prevalence of short stature among SGA children</u> was **9%** at one year of age (44% were preterm born), **6%** at 2 years, (60% preterm), **4%** at 3 years (33% preterm), **3%** at 4 years (no preterm). At 4 years of age median height SDS was -0.52 (IQR 0.31÷0.1), median BMI SDS was 0.04 SDS (IQR 0.15÷0.50). Only **1 child** born SGA was <u>eligible for GH treatment</u> (0.8% among SGA children) (she was not referred to endocrinologist).

	Although the prevalence of SGA in our population is similar to
	previous studies (3.1% in Finland, 3.5% in Japan, 5.5% in Sweden),
	data on catch-up growth are different from previous reports (8-12%
	without catch-up growth by 2 years of age). Moreover, 40% of short



CONCLUSIO

children at the age of 2 years in our cohort improved their height later, most of which born on term.

The prevalence of children born SGA who qualify for GH treatment was 1:3.250, much smaller than the prevalence reported in the only similar study conducted in Japan (1:1.800), with evaluation at 3 years. Height SDS of children born SGA at 4 years of age is lower than expected (-0.52 SDS).

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