FIVE YEARS OF GROWTH HORMONE THERAPY IN CHILDREN BORN SMALL FOR GESTATIONAL AGE

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INTRODUCTION

- Growth hormone (rhGH) is an effective treatment for short children born small for gestational age (SGA) who fail to demonstrate catch-up growth by 2-4 years of age
- This children usually don't have classical GH deficiency, but either low GH secretion or reduced sensitivity to GH
- The goals of therapy are to achieve a normal height in early childhood and an adult height within the normal target range

OBJECTIVES

- The primary objective was to evaluate growth during the first 5 years of rhGH treatment in 10 SGA children
- The secondary objectives of this study include:
  - registering the incidence and severity of adverse events
  - occurrence of malignancies during treatment

METHODS

- The study enrolled 10 SGA children : 6 boys and 4 girls
- All patients were given a mean dose of 0.035mg/kg/d and followed for a perioud of minimum 5years (mean 5.68 ys)
- We register the following parameters baseline and every 6 months:
  - height (cm and SD)
  - weight
  - height velocity (HV)
  - X-ray of non-dominant hand and wrist for bone age
  - IGF-1 values (ng/ml and SD)
  - glucidic profile (fasting plasma glucose, HbA1c, oral glucose tolerance tests)
  - thyroid status (TSH, FT4, ultrasound)
- All adverse events were registered at every visit

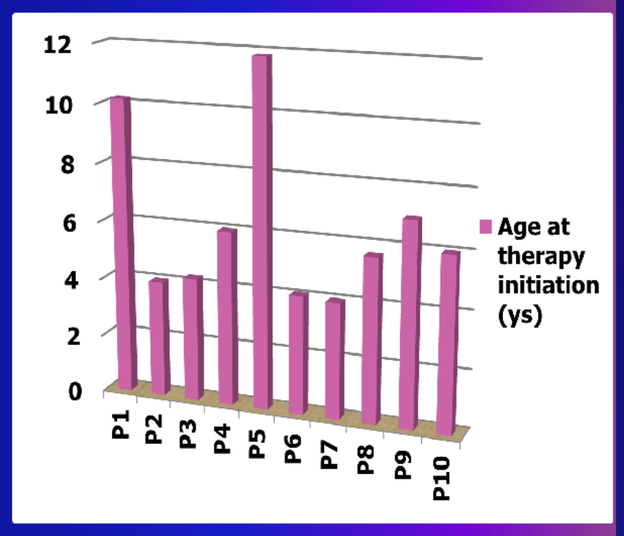

Figure 1. Age at rhGH therapy initiation

RESULTS

- The mean height standard deviation score (SDS) improved by 2.71, from -2.43 at baseline to +0.28 at 5 years of therapy; the changes in height SDS decreased with time (fig.2)
- Mean height velocity was maximum in the first year (11.76 cm/yr), decreasing in the second (9.24 cm/yr), third (8.16 cm/yr), fourth (7.68 cm/yr) and fifth year of treatment (6.24 cm/yr) (fig.3)

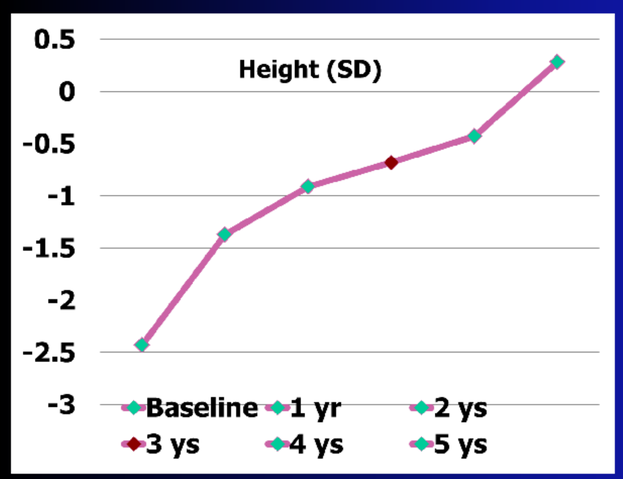

Figure 2. Height (SD) during first 5 years of rhGH therapy

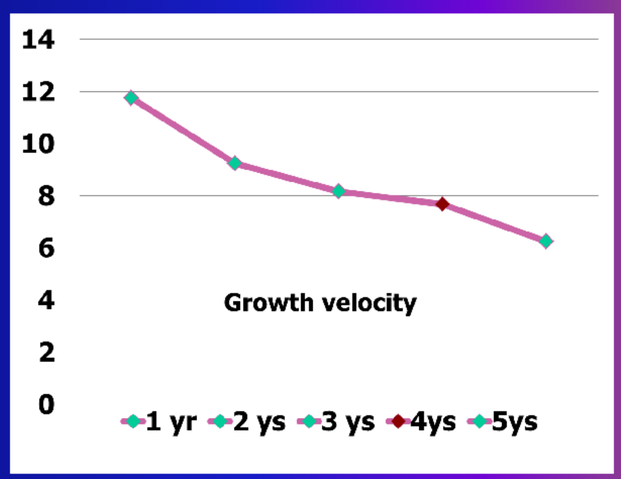

Figure 3. Growth rate durig the first 5 years of rh GH treatment

RESULTS

- Chronological age at therapy initiation varied between 4 and 12 years (mean 6.29 ys) (fig.1)
- Bone age at diagnosis was late by a mean value of 2.24 years, decreasing after 5 years of treatment at a mean value of 0.24 years (fig.4)
- Mean IGF-1 values were higher than normal range, but not exceeding +2DS (fig.5)

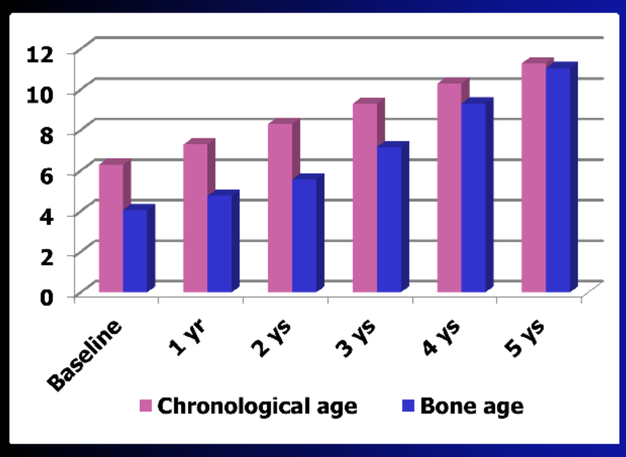

Figure 4. Evolution of bone age during first 5 years of therapy

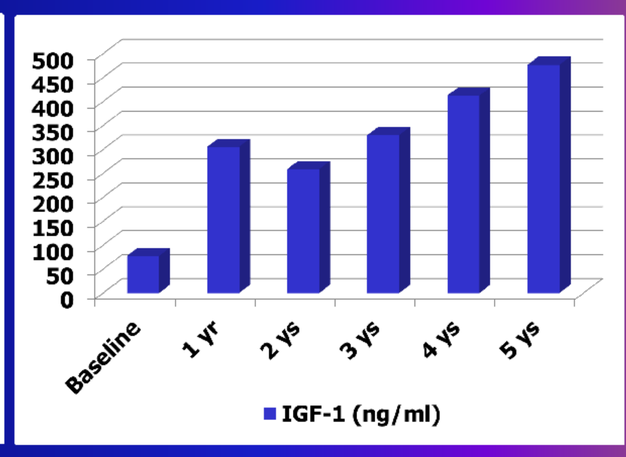

Figure 5. IGF-1 values during first 5 years of treatment

- In the first 5 years of therapy (fig.6) :
  - there were no cases of diabetes mellitus or impaired glucose tolerance (glucose between 140-200 mg/dl at OGTT; normal values of HbA1c)
  - 2 patients (20%) presented impaired fasting glucose (fasting glucose between 100-126 mg/dl)
  - 1 patient (10%) developed hypothyroidism
  - 4 patients (40%) presented transitory subclinical hypothyroidism (elevated TSH, normal FT4 values, no clinical signs)

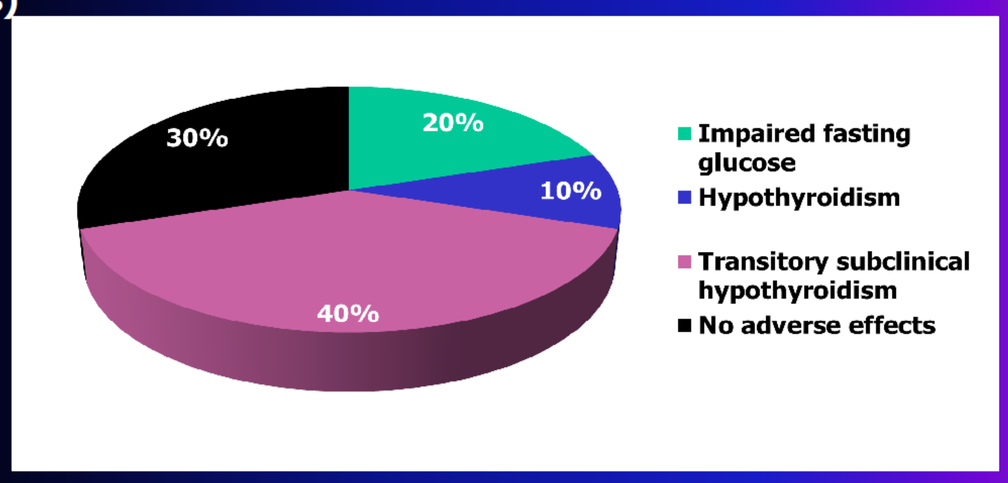

Figure 6. Adverse events during first 5 years of rhGH treatment

DISCUSSIONS

- Early initiation of rhGH therapy has as result the complete recovery of statural deficit in 5 years, according to growth prognosis calculated by parental heights
- Affecting the carbohydrate metabolism, rhGH treatment may have diabetogenic potential, especially in SGA children wich are at risk of developing type 2 diabetes

CONCLUSIONS

- GH therapy is reasonably safe and effective in increasing linear growth in children born SGA who fail to have catch-up growth
- Maximum height velocity was registered in the first year of treatment, 11.76 cm/yr and declined in time
- No severe adverse events were registered
- No malignancies were observed to date
- Overall, GH treatment was safe and well tolerated

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