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Easypod™ Connect Observational Study: The Italian Experience

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INTRODUCTION

Recombinant human growth hormone (r-hGH) is indicated to normalize statural growth and improve metabolic parameters in children with GH deficiency (GHD) and other clinical conditions[1]. GH treatment requires regular injections for a long period of time.

Adherence to treatment may affect response to GH. Non-adherent patients may not gain the physical and psychological benefits of GH treatment and may encounter later metabolic complications[2].

Therefore an early identification of non-adherence is essential to prevent future physical problems.

At the moment, the easypod™ device is the only electronic GH auto-injector available. Easypod™ enables accurate records of patients' adherence to recombinant human growth hormone (r-hGH) to be collected, providing real-world data for evaluation[3].

BACKGROUND

The Easypod Connect Observational Study (ECOS) is a prospective long-term observational study involving 24 countries aimed at evaluating the level of adherence in patients receiving growth hormone via the easypod™ device (Figure 1)[4].

Figure 1. ECOS

Design	Long-term, observational, open-label study
Location	24 countries
Duration	5 years (November 2010-February 2016)
Indications	Growth hormone deficiency, small for gestational age, Turner syndrome, other indications
Primary objective	To assess the level of adherence of participants receiving Saizen® via easypod™
Secondary objective	To describe the impact of adherence on clinical outcomes for participants receiving Saizen® via easypod™ To identify participant adherence profiling

OBJECTIVE

The study presents three years prospective adherence data from the Italian cohort of ECOS patients naïve to treatment.

METHODS

Patients and study design

Italian ECOS cohort of naïve GHD patients. A total of 73 patients were analyzed: 70 idiopathic, 2 organic and 1 congenital. Their main clinical characteristics are summarized in Table 1.

Table 1. Baseline patient demographic data

	Overall n=73	
Age, years	Mean (SD) Median Q1; Q3 Min; Max	9.78 (3.20) 10.00 8.00; 12.00 1.0; 15.0
Sex, n (%)	Female Male	35 (47.9) 38 (52.1)
Ethnicity, n (%)	African Caucasian	1 (1.4) 72 (98.6)
Height SDS at Baseline	Mean (SD) Median Q1; Q3	–2.40 (0.73) –2.34 –2.80; –1.96

All patients received r-hGH (Saizen®, Merck KGaA, Darmstadt,Germany) via the easypod™ device.

The adherence rate was calculated as follows:

$$\text{Treatment adherence rate (\%)} = \frac{\text{Number of days injections received during period}}{\text{Number of days injections planned during period}} \times 100$$

Statistical analysis

Height standard deviation score (SDS) was calculated using World Health Organization reference data[5] and height velocity (HV) SDS was calculated using Tanner growth standards[6]. The impact of adherence rates on clinical outcomes at the end of 1 year of treatment was analyzed using Spearman's product-moment correlations.

RESULTS

Adherence

Data were available for 65 patients after 1 year, for 40 after 2 years and for 18 after 3 years (Figure 2). The median level of adherence was maintained >80% over 3 years (Figure 3).

Figure 2. Number of patients with prospective adherence data over the study period

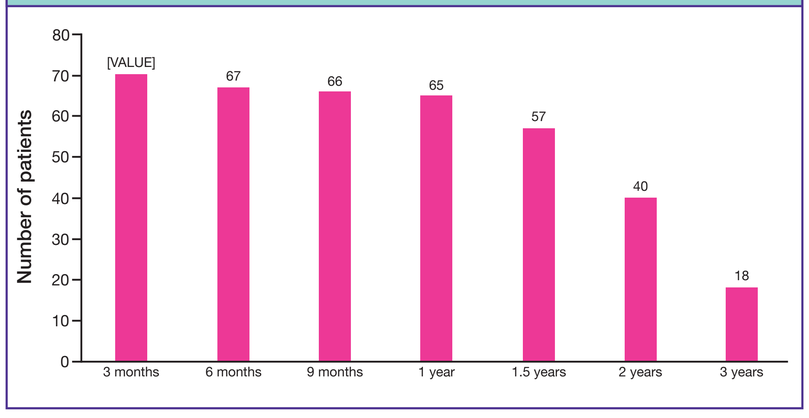

Figure 3. Treatment adherence rates over time in the easypod™ adherence data analysis.

Growth Outcome

Median change in height SDS after 1 year was 0.41 (Table 2). This level of adherence was not correlated with parameters of growth outcome by Spearman's product-moment correlation likely due to adherence values being skewed towards high positive levels. Additional modelling is expected to provide further insights on correlations between adherence and outcomes.

Table 2. Growth response after 1 year of treatment in naïve GHD patients

	Overall n=70	
Change in height SDS	Mean (SD) Median Q1; Q3	0.42 (0.38) 0.41 0.18; 0.61

CONCLUSIONS

- **The majority of patients starting GH treatment with easypod™ maintained adherence >80% up to 3 years.**
- **ECOS has produced accurate, robust, and real-time adherence data in patients receiving Saizen® via easypod™ and provided useful insights into growth response to Saizen® treatment.**
- **Using easypod™ and easypod™ Connect, physicians can identify patients with inadequate adherence, and with poor response to treatment, and help them maximize the benefits of recombinant human GH treatment**
- **Overall growth response was positive and clinically meaningful**

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DISCLOSURES

SL is a member of the ECOS International Steering Committee

CC is an Employee of Merck-Serono - Rome

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