ACROSTART: Spanish retrospective study to determine the timeframe to achieve hormonal control with initial Lanreotide Autogel treatment in acromegaly patients in routine clinical practice

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Introduction

- Acromegaly is a rare, chronic endocrine disease, characterized by enhanced growth hormone (GH) secretion and elevated insulin-like growth factor-I (IGF-I) levels, the most frequent cause of which is a pituitary adenoma2
- Persistently elevated GH and IGF-I levels lead to substantial morbidity and mortality2
- Control of GH and IGF-I secretion is decisive in improving survival1 and optimum management of the disease requires a reduction in GH levels to ≤2.5 ng/ml and normalisation of IGF-I levels2
- Somatostatin analogues (SSAs) have become the pillar of acromegaly medical therapy in patients unsuitable for, or refusing surgery, after failure of surgical treatment, or in selected cases as primary treatment1
- The primary objective was to determine the timeframe to achieve hormonal control (defined as GH levels <2.5 ng/ml and/or normalised IGF-I on ≥2 consecutive evaluations) considering the starting dose and dosage intervals of Lanreotide Autogel commonly used in clinical practice
- The following were secondary objectives:
  - To determine use of healthcare resources until obtaining hormonal control
  - To assess the efficacy of Lanreotide Autogel in controlling tumour size in daily clinical practice
  - To evaluate patients’ general satisfaction with Lanreotide Autogel therapy
  - To determine the use of healthcare resources until obtaining hormonal control
- The PAS population consisted of 57 patients with a median age of 64 years (range 23-90). Demographic characteristics are shown in Table 1

Results

- 62 patients were screened from 08 March to 31 October 2013. Five patients were excluded from the primary analysis set (PAS) because they underwent surgery or received radiotherapy between the initiation of treatment with Lanreotide Autogel and achieving hormonal control
- The PAS population consisted of 57 patients with a median age of 64 years (range 23-90). Demographic characteristics are shown in Table 1
- 22.8% of the patients managed injections without assistance of healthcare staff, either with self-injections or with Lanreotide Autogel and achieving hormonal control
- 30.5% of the patients were able to self-inject
- The decision to prescribe Lanreotide Autogel was made prior to and independently from the patient’s enrolment into the study and it was prescribed according to routine clinical practice
- Study included adults with active acromegaly who had been treated with Lanreotide Autogel for at least 4 months, with GH levels >2.5 ng/ml and/or normalised IGF-I on at least two consecutive evaluations
- Patients whose clinical records lacked information regarding the date and initial dose of Lanreotide Autogel and the first hormonal response available were excluded
- Descriptive statistics summarised quantitative variables
- All patients provided written informed consent

Objectives

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Methods

- This was a multicentre, non-interventional, retrospective, post-authorisation study performed in 62 adult patients with active acromegaly conducted at 17 centres in Spain
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Table 1. Patient demographics and disease characteristics

<table>
<thead>
<tr>
<th>PAS n=57</th>
<th>60 mg/4 wks</th>
<th>50 mg/5 wks</th>
<th>120 mg/4 wks</th>
<th>60 mg/8 wks</th>
<th>120 mg/8 wks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male, n (%)</td>
<td>21 (36.8)</td>
<td>4 (30.8)</td>
<td>11 (16.7)</td>
<td>6 (42.9)</td>
<td>3 (33.3)</td>
</tr>
<tr>
<td>Female, n (%)</td>
<td>36 (63.2)</td>
<td>16 (70.2)</td>
<td>39 (83.3)</td>
<td>24 (57.1)</td>
<td>22 (66.7)</td>
</tr>
<tr>
<td>Patient able to self-inject, n (%)</td>
<td>14 (44.7)</td>
<td>3 (19.4)</td>
<td>9 (33.3)</td>
<td>2 (15.4)</td>
<td>0</td>
</tr>
<tr>
<td>Injection by healthcare staff</td>
<td>21 (58.3)</td>
<td>8 (50)</td>
<td>4 (66.7)</td>
<td>9 (75)</td>
<td>12 (100)</td>
</tr>
<tr>
<td>Injection by staff family member</td>
<td>20 (95.2)</td>
<td>7 (58.3)</td>
<td>4 (66.7)</td>
<td>9 (75)</td>
<td>12 (100)</td>
</tr>
<tr>
<td>Type of adenoma, n (%)</td>
<td>Microadenoma &lt;10 mm, macroadenoma &gt;10 mm. PAS, Primary Analysis Set.</td>
<td></td>
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<tr>
<td></td>
<td>Microadenoma</td>
<td>22 (38.6)</td>
<td>8 (51.3)</td>
<td>2 (33.3)</td>
<td>6 (46.2)</td>
</tr>
<tr>
<td></td>
<td>Macroadenoma</td>
<td>35 (61.4)</td>
<td>8 (28.6)</td>
<td>16 (66.7)</td>
<td>7 (53.3)</td>
</tr>
<tr>
<td>Prior treatment, n (%)</td>
<td>Not at all</td>
<td>30 (52.6)</td>
<td>13 (68.4)</td>
<td>27 (81.8)</td>
<td>16 (50)</td>
</tr>
<tr>
<td>Surgery</td>
<td>8 (14.0)</td>
<td>2 (15.4)</td>
<td>2 (6.7)</td>
<td>3 (25)</td>
<td>2 (6.7)</td>
</tr>
<tr>
<td>Imaging tests</td>
<td>13 (23.2)</td>
<td>5 (26.3)</td>
<td>5 (15.6)</td>
<td>7 (58.3)</td>
<td>6 (18.7)</td>
</tr>
<tr>
<td>Adrenocortical axis before treatment</td>
<td>GHRH, nG/ml, mean (95% CI)</td>
<td>5.0 (2.6; 7.4)</td>
<td>4.2 (3.7; 4.7)</td>
<td>11.3 (9.1; 13.5)</td>
<td>6.8 (5.2; 8.4)</td>
</tr>
<tr>
<td></td>
<td>%ULN of IGF-1, mean (95% CI)</td>
<td>2.6xULN (1.7; 5.0)</td>
<td>1.3xULN (0.7; 2.2)</td>
<td>3.3xULN (1.7; 5.0)</td>
<td>2.8xULN (1.6; 5.0)</td>
</tr>
</tbody>
</table>

Conclusions

- In a real-life setting, the median time elapsed between initiating treatment with Lanreotide Autogel and achieving hormonal control was 4.9 months with 120 mg being the most widely used starting dose.
- One fifth of the patients managed injections without assistance of healthcare staff.
- Patients with a high treatment adherence and treatment satisfaction, despite disparity of starting doses and dosage interval.

References