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Dose interval injection extension and costs of lanreotide Autogel 120 mg used in routine acromegaly care in Poland – 2-year data from the Lanro-Study

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Introduction

- Lanreotide Autogel 120 mg, a long acting analogue of natural somatostatin, is administered every 28 days and may be given at increased intervals of 6-8 weeks in patients in whom clinical symptoms of acromegaly and biochemical parameters are adequately controlled with the monthly dose.1
- The possibility of extending dosing intervals of drugs administered in injections may positively influence patient treatment preference, compliance and quality of life.1-5
- The aim of the Lanro-Study was to evaluate, over 24 months' prospective follow-up, the dosage and costs of lanreotide Autogel 120 mg (ATG120) administered as part of routine acromegaly care in Poland.

Methods

- The Lanro-Study is a national, multicentre, noninterventional, observational prospective study.
- The study was conducted in accordance with the Declaration of Helsinki⁶ and the International Ethical Guidelines for Epidemiological Studies⁷ and followed the recommendations of the International Society for Pharmacoepidemiology (ISPE) Good PharmacoEpidemiological Practices (GPP) Guidelines.8
- Adult patients with acromegaly who received at least three injections of ATG120 before assessment and who gave written informed consent before entering the study were included.
- Data were collected prospectively over 24 months.
- Endpoints were percentage of patients treated with ATG120 at an extended duration interval (>4 weeks) and mean cost of ATG120 during the 24 months' follow-up.
- Costs were calculated in PLN from the public health-care payer and patient perspective for the year 2014 (1 PLN=0.25 EURO).

Results

Patient population

- A total of 151 patients suffering from acromegaly for at least 1 year were screened and 143 enrolled in 35 centres.
 - Of these, 11 patients were excluded from the analysis due to missing follow-up visits or because they did not complete the treatment period.
- Baseline demographic and clinical characteristics of the population included in the analysis (n=132) are summarized in Table 1.
- At the time of inclusion 54% of patients with growth hormone (GH) data (n=101) achieved biochemical control of their disease, defined in this study as GH ≤2.5 ng/mL.

Treatment with ATG120 during 2 years of tollow-up

 The mean/median number of days between injections over the 24 months was 35.1 (SD 8.2)/31.

Table 1. Baseline demographic and clinical characteristics of the patient population included in the analysis (n=132).

Variable	Population		
Age, mean (SD), years	51.7 (14.3)		
Weight, mean (SD), kg	82.8(17.7)		
BMI, mean (SD), kg/m²	29.4(5.4)		
Sex			
Male, n (%)	39 (29.5)		
Female, n (%)	93 (70.5)		
Tumour size at diagnosis			
Macroadenoma (≥10 mm in diameter), n (%)	108 (81.8)		
Microadenoma (<10 mm in diameter), n (%)	18 (13.6)		
Not known: n (%)	6 (4.6)		
Tumour diameter, mean (SD), mm	19.2 (11.2)		
Comorbidity			
Diabetes mellitus, n (%)	40 (42.1)		
Hypertension, n (%)	78 (82.1)		
Cholelithiasis, n (%)	26 (27.4)		
Treatment history			
Pituitary surgery, n (%)	99 (75)		
Time since surgery, mean (SD), years	7.7 (6.7)		
Radiotherapy, n (%)	23 (17.4)		
Time since radiotherapy, mean (SD), years	8.1 (6.5)		
ATG120 injections every 4 weeks at inclusion (data for injection intervals was available for n=87 patients), n (%)	66 (46.2)		

- Sixty-three patients (48%) received ATG120 at an extended dosing interval (>4 weeks), predominantly every 5 weeks (n=28) or every 6 weeks (n=19).
- Dosing intervals set at the beginning of the study remained the same for 91 patients (69.6%) until study end.
- Changes in dosing regimen of ATG120 in clinical practice were reported by 41 patients (30.4%) (Table 2).
- 97% of injections were administered by a healthcare professional (84% nurses and 17% physicians) of which 84% were performed in an out-patient setting.
- The number of unsupervised home injections was only 76 (2.6% of the total number of injections).

Table 2. Changes in dosing regimen.

Type of change	Number of patients
Interval increased	7
Interval shortened	12
Interval alternately extended or shortened	18
Switching from ATG120 every 4 weeks to octreotide LAR 30 mg every 4 weeks and then to ATG120 every 4 weeks	1
Switching from ATG120 every 4 weeks to octreotide LAR 30 mg every 4 weeks	1
Switching from ATG120 every 4 weeks to octreotide LAR 20 mg every 4 weeks, then to octreotide LAR 30 mg every 4 weeks and then to ATG 120 every 4 weeks	1
Switching from ATG120 every 5 weeks to octreotide LAR 30 mg every 4 weeks, and then to ATG 120 every 4 weeks	1

Cost of treatment

 The mean cost of ATG120 per patient/month was 4062.5 PLN (1015.6 Euro) and 3.6 PLN from the public payer and patient perspective, respectively (Table 3). Meanwhile the retail price per pack of ATG120 is 4770.5 PLN (1192.6 Euro).

Table 3. Mean dosing regimen and cost of ATG120 during 24 months' observation (n=132).

				Cost/PLN/month*			
	Dose	Interval (weeks)	Patients (n)		Public payer + patient	Public payer	Patient
Lanreotide Autogel	120 mg	4	69		4066.13	4062.49	3.64
		5	28				
		6	19	122			
		7	7	132			
		8	8				
		9	1				

at 1 of November 2014.94066.13 PLN correspond to 1016.5 Euro, 4062.49 PLN correspond to 1015.6 Euro.

Conclusions

 Two years' observation of a substantial group of patients suffering from acromegaly in Poland indicates that lanreotide Autogel 120 is economically preferable due to the extended dosing interval (cost of ATG120 retail price 4770.25 PLN vs. mean cost per month of 4066.13 PLN) used in almost half of the patients.

Lanro-Study investigators

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