



Patient satisfaction and preferences of lanreotide Autogel treatment in acromegaly

Satysfakcja i preferencje pacjentów dotyczące leczenia lanreotydem Autogel w akromegalii

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Abstract

Introduction: Despite the known importance of somatostatin analogues (SSAs) in the treatment of acromegaly, patient satisfaction leading to preferences for specific SSAs have received little attention so far.

Material and methods: This open, prospective, observational, multicentre patient-reported outcome study included adult patients with acromegaly, who switched from another SSA to lanreotide Autogel (new and previous devices) at least two months prior to enrolment. The observation period was around 12 months. The primary outcome assessed was overall treatment satisfaction, measured using the five-point Likert scale. The secondary outcomes were: 1) treatment effectiveness, in terms of symptom control; 2) technical problems related to treatment administration, measured by the Visual Analog Scale (VAS); and 3) ease and safety of lanreotide Autogel delivery (new device *vs.* previous device).

Results: Of the 102 patients who completed the study, 97 (95.1%) were “completely or rather satisfied” with lanreotide Autogel therapy, four (3.9%) were “neither satisfied nor dissatisfied”, and one (1%) was “rather dissatisfied”. Symptom control was reported as “excellent” or “good” by 88–89% of patients throughout the study. Patients reported fewer technical problems related to administration of lanreotide Autogel (final mean VAS: 5.3) compared to previous SSAs (mean VAS: 37.6). Of the 31 patients treated with lanreotide Autogel using the previous device followed by the new device, 64.5% reported the new device as improved.

Conclusions: Lanreotide Autogel therapy resulted in greater patient satisfaction with overall acromegaly management, when compared to previous SSAs. The new lanreotide Autogel device was found to be easier to use than the previous one. (*Endokrynol Pol* 2016; 67 (6): 572–579)

Key words: acromegaly; somatostatin analogues; lanreotide; octreotide; patient preferences; observational study

Streszczenie

Wstęp: Pomimo znanego znaczenia analogów somatostatyny (SSA) w leczeniu akromegalii, dotychczas nie poświęcono wiele uwagi zadowoleniu pacjenta i preferencjom dotyczącym poszczególnych SSA.

Materiał i metody: Było to otwarte, prospektywne, obserwacyjne, wieloośrodkowe badanie, oparte na samoocenie przez pacjenta wyników leczenia. Obejmowało dorosłych pacjentów z akromegalią, którzy zmienili inny SSA na lanreotyd Autogel (nowe i stare aplikatory), co najmniej 2 miesiące przed włączeniem do badania. Okres obserwacji wynosił około 12 miesięcy.

Podstawowym ocenianym wynikiem była ogólna satysfakcja z leczenia, mierzona za pomocą 5-punktowej skali Likerta. Wyniki uzupełniające były następujące: 1) efektywność leczenia pod względem kontroli objawów; 2) problemy techniczne związane z podawaniem leku, mierzone za pomocą wizualnej skali analogowej (VAS); i 3) łatwość i bezpieczeństwo stosowania lanreotydu Autogel (nowe urządzenie *vs.* stare urządzenie).

Wyniki: Spośród 102 pacjentów, którzy ukończyli badanie, 97 (95,1%) było “w pełni lub raczej zadowolonych” z terapii lanreotydem Autogel, czterech (3,9%) było “ani zadowolonych, ani niezadowolonych”, a jeden był “raczej niezadowolony”. Kontrola objawów była oceniona jako “doskonała” lub “dobra” przez 88–89% pacjentów w całym badaniu. Pacjenci zgłaszali mniej problemów technicznych związanych z podawaniem lanreotydu Autogel (końcowa średnia VAS: 5,3) w porównaniu z poprzednimi SSA (średnia VAS: 37,6). Spośród 31 pacjentów leczonych lanreotydem Autogel korzystających ze starego urządzenia, a następnie z nowego, 64,5% oceniło nowe urządzenie jako lepsze.

Wnioski: Terapia lanreotydem Autogel skutkowała większym zadowoleniem pacjentów z ogólnego postępowania w akromegalii, w porównaniu z poprzednimi SSA. Nowe urządzenie do aplikowania lanreotydu Autogel okazało się łatwiejsze i bezpieczniejsze w użyciu niż poprzednie. (*Endokrynol Pol* 2016; 67 (6): 572–579)

Słowa kluczowe: akromegalia; analogi somatostatyny; oktreotyd; lanreotyd; preferencje pacjenta; badanie obserwacyjne

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Introduction

Acromegaly is a chronic disease, caused by growth hormone (GH) secreting pituitary adenoma, which in turn results in overproduction of insulin-like growth factor-1 (IGF-1). It leads to typical clinical symptoms as well as metabolic and cardiovascular complications, and largely impaired quality of life (QoL) [1]. The mortality rates in patients with untreated or poorly controlled acromegaly are increased compared with the general population [2]. Thus, effective therapy is key to reversing biochemical abnormalities, ameliorating symptoms, and ultimately restoring patient well-being, normal personal and societal functioning, as well as increasing life expectancy.

Surgery is the first-line treatment of acromegaly and often is followed by pharmacological therapy and radiotherapy [3]. Transsphenoidal resection of a pituitary tumour either removes or substantially decreases the size of the tumour, thus preventing intracranial complications [1]. When surgery cannot be performed or is unsuccessful, whether because of a non-fully resectable tumour, clinical contraindications, or patient refusal, alternative therapies must be considered. One such pharmacological alternative is the somatostatin analogues (SSAs): long-term SSA treatment has been shown to be effective both in terms of hormonal normalisation and tumour shrinkage [4, 5]. Nowadays, three SSAs (lanreotide, octreotide, and pasireotide) are available in Poland. All are effective in decreasing GH secretion and IGF-1 levels [6]; however, there have been no head-to-head studies. In a small, randomised crossover study, Andries et al. showed comparable effects of lanreotide and octreotide on biochemical control of acromegaly in some, but not all, patients. At the same time, the authors observed various response profiles in a proportion of their study population, leading them to the conclusion that a change from one drug to another maybe beneficial in patients displaying poor treatment response or side effects [7].

In light of the burden of long-term parenteral treatment, patient treatment perception is critical, primarily for adherence to treatment and thus for achieving optimal treatment effects [8]. To accurately gauge patient preference, a survey of patient-reported outcomes is considered preferable, as it helps determine the efficacy of treatment and interpret clinical results from a patient's perspective, and it supports the treating physician in making decisions about the patient's therapy. Overall patient preference, especially in the case of chronic disorders, is a mandatory component of current models of shared doctor-patient decision making [9]. Despite the known importance of this aspect of patient treatment, very little has been published on this issue in terms of acromegaly [10–12].

Nevertheless, it should be noted that treatment preference is a notion specific to culture and the mentality of the societal setting, and one that is dependent on the health care system. Therefore, it is important that it is studied in a certain sociocultural context [13]. A better understanding of treatment preference specific for the Polish population of patients with acromegaly is of importance in enhancing patient adherence to treatment and, in turn, patients' health outcomes [14].

Our study aims at broadening our knowledge by assessing treatment preference in adult patients with acromegaly, who were being treated with lanreotide Autogel, after having switched from other SSAs.

Material and methods

The study presented herein was designed as an open, prospective, observational, non-interventional, multi-centre, patient-reported outcome study. All local regulatory requirements applicable to non-interventional studies were fulfilled; approval by the Local Ethics Committee was sought and confirmed. This study followed the recommendations of the Declaration of Helsinki (2008), as well as relevant epidemiological guidelines [15–17].

Eligibility for participation in the study was assessed during routine outpatient visits. Adult patients with acromegaly were included to the study, if they were switched from octreotide to lanreotide as of January 1, 2012, and treated with lanreotide Autogel (including a new type of device) for at least two months prior to enrolment in the study. The decision to prescribe lanreotide Autogel was made prior to and independently from the decision to enrol patients to this study. Participants were notified of the details of the study by their treating physician, and provided written informed consent to participate in the study. To preserve transparency, investigators included consecutive subjects to achieve the recruitment target (targets per centre). The choice of centres was based on the ability to collect the data, motivation to participate in the study, and fulfilling the requirements of the protocol.

The observation period for each participant was approximately 12 months. Data were collected during four visits: one enrolment visit (V0) and three follow-up visits (V1, V2, and V3), each of which was held within four months of the previous visit. No additional assessments or tests were required. Treatment monitoring, dose adjustment, and all other medical decisions were made at the discretion of the treating physician, and all assessments and procedures were conducted in accordance with routine medical practice at the study site. Therefore, participation in the study did not expose the subjects to additional risks or burdens.

The primary study objective was to assess patients' satisfaction with, and thus indirectly preference for, lanreotide Autogel treatment compared with previous SSA. The secondary objective was to assess patients' preference for a new lanreotide Autogel device (new pre-formulated preparation in a pre-filled syringe; 1.2 mm needle for all doses, including a rigid needle cap, automatic needle guard to prevent needle-stick injuries, and a fully transparent delivery system) compared with the previous lanreotide Autogel device.

Several items were recorded at the enrolment visit: demographic details, relevant medical history, and prior treatment including surgery and medication. Data on previous use of SSAs, with a focus on SSA treatment regimen and reasons for the change in treatment, were collected. Information relating to the current medical therapy, in particular the use of lanreotide Autogel (dose, frequency, details of administration), was gathered at each visit.

The primary study endpoint was overall treatment satisfaction with lanreotide Autogel assessed at the end of the study using the five-point Likert scale (from completely satisfied to completely dissatisfied). The secondary endpoints were: 1) lanreotide Autogel treatment effectiveness in terms of acromegaly symptom control (five-point Likert scale: excellent, good, acceptable, poor, and very poor); 2) technical problems related to administration of lanreotide Autogel, as measured by the Visual Analogue Scale (VAS), anchored as "no technical problems" — coded as 0, and "technical problems" — coded as 100); and, 3) the ease of injecting lanreotide Autogel from a new type of device and the safety of the pre-filled syringe. Technical problems related to drug administration and the ease of injecting lanreotide Autogel were evaluated either by patient/partner or doctor/nurse, depending on who administered the drug.

Statistical analysis was performed using Statistical Analysis System (SAS) version 9.2. Data are presented as descriptive summary statistics (n, mean, standard deviation [SD]) or frequency counts (percentage [%]).

Results

Patient characteristics

Of 114 patients screened, 113 (aged 18–80 years; 40.7% men) were enrolled in the study. Over the 12-month follow-up, 11 patients withdrew from the study (one due to adverse event, one due to lack of efficacy, and nine were lost to follow-up) (Fig. 1). The mean (SD) duration of study participation was 10.3 (2.51) months, and the mean (SD) duration of treatment with lanreotide Autogel was 15.4 (9.59) months. The demographics of the enrolled population are summarised in Table I. In

the studied population, 47 subjects (41.6%) reported comorbidities, with the most common being diabetes mellitus (n = 30; 26.5%). Other reported comorbidities included: kidney diseases (n = 8; 7.1%), congestive heart failure (n = 6; 5.3%), cerebrovascular disease, and cancer (n = 5; 4.4% each). Concomitant disorders such as chronic obstructive pulmonary disease, history of gastric ulcers, liver disease, myocardial infarction, and peripheral vascular disease were reported in single subjects.

As far as prior therapy is concerned, 74 (65.5%) individuals underwent at least one pituitary surgery (53 patients with one surgery, 20 patients with two surgeries, and one patient with three surgeries). During the enrolment visit, 11 (9.7%) patients reported having been previously treated with dopamine agonists (bromocriptine or cabergoline) in addition to other SSAs. During the study 19 patients took one or more pituitary directed medication other than lanreotide Autogel; these included: dopamine agonists (n = 19; 16.8%), and temozolomide (n = 1; 0.9%).

All subjects were treated with a deep subcutaneous injection of lanreotide Autogel 120 mg in the conditions of everyday clinical practice. In almost 70% of cases, at each visit, a nurse in an outpatient clinic administered the drug. A minority of patients received lanreotide Autogel in hospital (17.1% at V1 and 15.7% at V3) or at home (13.5% at V1 and 15.7% at V3). Of these home-administrations, approximately 10% of patients self-administered and 4% were administered the drug by their partners.

The most common reason for a change in therapy from octreotide to lanreotide was unsatisfactory self-reported efficacy of the original treatment (n = 50; 44.2%). Approximately one-third of patients (n = 38; 33.6%) changed treatments because of the high cost of octreotide therapy resulting from the government reimbursement policy in this period. Thirty-one (27.4%) patients changed therapies based on their personal choice. Table II summarises the reasons patients decided to switch therapies.

A total of 53 (46.9%) patients were treated first with lanreotide Autogel delivered as pre-filled syringe (old device) followed by lanreotide Autogel as new device. The remainder (n = 60; 53.1%) only received lanreotide Autogel in the new delivery device.

Assessment of overall satisfaction with treatment

At the end of the study, 97 (95.1%) participants were either "completely satisfied" or "rather satisfied" with the lanreotide Autogel treatment, four (3.9%) were "neither satisfied nor dissatisfied", and just one patient was "rather dissatisfied". None of the patients who completed the study were "completely dissatisfied".

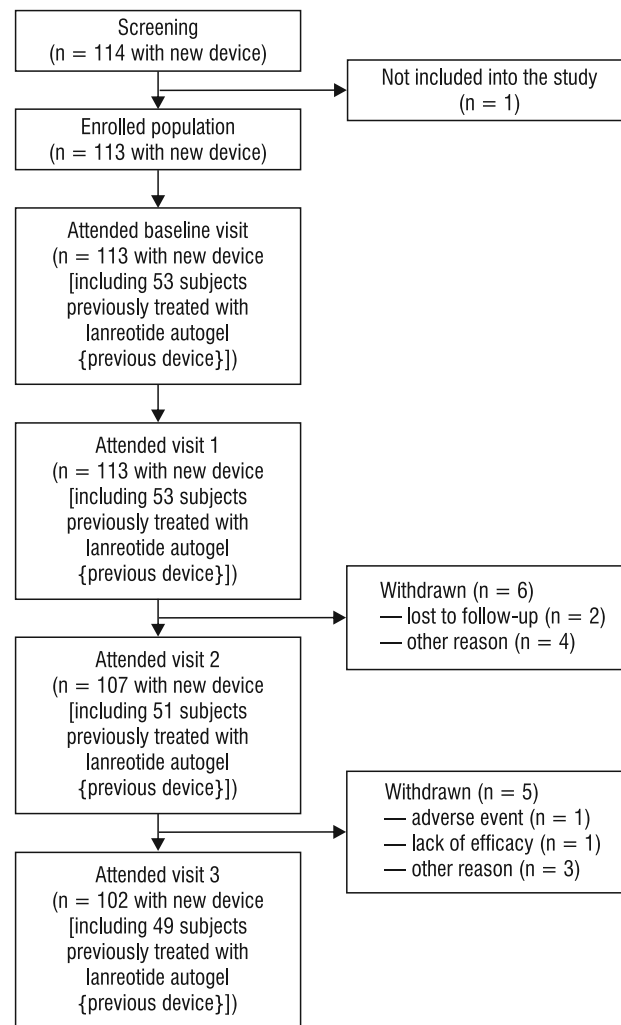


Figure 1. Patient flow during the study

Rycina 1. Przepływ pacjentów podczas badania

Table I. Patient demographic and clinical characteristics at baseline

Tabela I. Demograficzne i kliniczne cechy chorych na początku badania

Age [years; mean (SD)]	53.7 (12.9)
Height [cm; mean (SD)]	170.1 (9.6)
Weight [kg; mean (SD)]	86.3 (18.0)
Female [n (%)]	67 (59.3)
Time since acromegaly diagnosis [years; mean (SD)]	7.9 (7.92)
Previous pituitary surgery [n (%)]	74 (65.5)
Pituitary surgeries [n; mean (SD)]	1.3 (0.5)
Time since last pituitary surgery [years; mean (SD)]	7.9 (6.92)

Overall, 97 (95.1%) patients stated that they would like to continue with the lanreotide Autogel treatment after the completion of the study, with the remainder (n = 5; 4.9%) wishing not to continue.

Assessment of effectiveness of treatment with SSA

At baseline, 54% of subjects assessed the effectiveness of previous SSAs in terms of control of acromegaly symptoms as either “excellent” or “good”. At the completion of the current study, 88–89% of subjects assessed the effectiveness of lanreotide Autogel as either “excellent” or “good” (Table III).

Assessment of technical problems relating to SSA administration

Figure 2 summarises the VAS scores related to technical problems of prior SSA administration in comparison to lanreotide Autogel. The mean (SD) VAS score for octreotide was 37.6 (26.5), and ranged from 0 to 88. Data for VAS scores relating to technical problems of administration of lanreotide Autogel were collected at each visit. A mean (SD) VAS score of 7.4 (11.7) was recorded at the enrolment visit; however, this decreased to a mean (SD) of 5.3 (8.5) at the last visit (V3).

Table II. Reasons for change of treatment from octreotide to lanreotide Autogel

Tabela II. Przyczyny zmiany leczenia oktreotydem na lanreotyd Autogel

Reason	n (%)
Unsatisfactory efficacy	50 (44.2)
Cost of treatment	38 (33.6)
Patient's decision	31 (27.4)
Injection site reactions	18 (15.9)
Unsatisfactory safety	6 (5.3)
Other reasons	24 (21.2)

Assessment of treatment with lanreotide Autogel using the new device

The subgroup of 53 subjects received the first lanreotide Autogel injections with an old device and with a new device afterwards. Thirty-one patients assessed the new lanreotide Autogel device, and 20 (64.5%) declared that the ease of usage had been improved. Most participants appreciated the user-friendly handling (n = 15) and simple manual (n = 12). For 11 patients there was no difference between the old and new devices. None of the study participants assessed usage of the new device as worse than the old device. Fifty investigators also assessed the usage of the new device, and 46 (92.0%) reported that the usage of the new syringe, compared to the previous pre-filled syringe, had been improved. Importantly, investigators appreciated the user-friendly handling of the new lanreotide Autogel device.

Discussion

In the current study, we showed that the majority of patients treated for a mean of 15 months with lanreotide Autogel 120 mg were satisfied with the treatment, found it to be effective in controlling acromegaly-spe-

cific symptoms, and did not report technical problems relating to drug administration. In addition, patients reported the new lanreotide Autogel injection device to be an improvement in comparison to the previous method. These results indicate that the degree of patient satisfaction may represent patient preference in terms of treatment. In light of current results, given that the majority of patients reported satisfaction with lanreotide Autogel therapy, patient preference for this treatment may also be implied. These findings are consistent with the results of the international LEAD study, where, for all dosing interval groups tested, at least three-quarters of patients (eight-week extended dosing interval: 92.3%; six-week extended dosing interval: 77.9%; four-week dosing interval: 76.9%) preferred the lanreotide Autogel treatment to octreotide at the final phase of the study [11]. In the LEAD report, 120 mg of lanreotide Autogel was shown to be well tolerated, with adverse effects reported to be only mild or moderate in severity. According to the patient-assessed acromegaly questionnaire (PASQ) used at baseline, during and at the end of the LEAD study, treatment had little effect on the perceived acromegaly symptoms. In the PASQ, five symptoms and signs were assessed: headache, excessive perspiration, fatigue, soft tissue swelling, and arthralgia [18].

In 2012, the administration of lanreotide was made markedly easier thanks to the introduction of a new syringe (injection device). This method of delivery reduces the risk of errors in reconstitution, and improves the predictability and reliability of accurate dose adjustment. Our findings of preference for the new lanreotide injection device also reflect those of another study, which interviewed nurses who administered SSAs. The study found nurses to have a greater appreciation for the ease and convenient preparation and injection method offered by the novel device. It also found it to offer a shorter mean preparation and administration time than the octreotide long-acting release device. Overall, the study showed the nurses to prefer the new

Table III. Effectiveness of SSAs on acromegaly symptom control

Tabela III. Skuteczność SSA w kontroli objawów akromegalii

	Octreotide	Lanreotide Autogel			
	N = 113 n (%)	V0 N = 113 n (%)	V1 N = 111 n (%)	V2 N = 107 n (%)	V3 N = 102 n (%)
Excellent	9 (8.0)	33 (29.2)	35 (31.5)	34 (31.8)	44 (43.1)
Good	52 (46.0)	66 (58.4)	63 (56.8)	60 (56.1)	47 (46.1)
Acceptable	39 (34.5)	11 (9.7)	9 (8.1)	10 (9.3)	9 (8.8)
Poor	11 (9.7)	2 (1.8)	3 (2.7)	3 (2.8)	2 (2.0)
Very poor	2 (1.8)	1 (0.9)	1 (0.9)	0	0
Missing	0	0	2	0	0

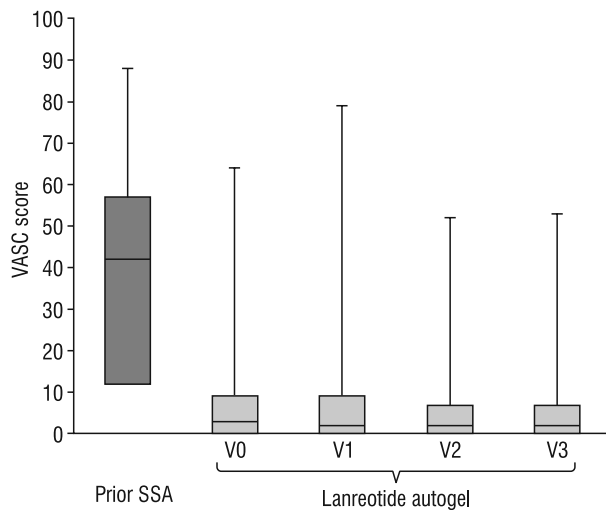


Figure 2. Technical problems related to prior SSA and lanreotide Autogel administration (data shown as mean, SD). VAS — Visual Analog Scale; SSA — somatostatin analog; V0, V1, V2, V3 — visit 0, 1, 2, 3

Rycina 2. Problemy techniczne związane z aplikowaniem wcześniejszego SSA i lanreotydu Autogel (dane przedstawione jako średnia, SD). VAS — wizualna skala analogowa; SSA — analog somatostatynny; V0, V1, V2, V3 — wizyty: 0, 1, 2, 3

lanreotide-administering device, not only for reasons of ease, convenience, and speed, but also for the reduced risk of clogging and improved dosage confidence [19]. From the patients' point of view, greater assurance of correct drug dosage upon administration may reduce the stress associated with receiving treatment, and may relieve concerns that the therapy could be unsuccessful due to incorrect dosing. Unsatisfactory efficacy was the most common reason patients decided to change medication, from octreotide to lanreotide, before being enrolled in our study. The development of the new syringe, which is both enhanced and easier to use than previous injection devices, may encourage patients to self-administer the drug; additionally, the convenience it offers may be attractive to subjects who wish to save time (by eliminating a trip to the doctor) or for those who live great distances from medical centres. Despite the ease of the novel device, many patients still choose not to self-administer. In our study, the drug was primarily administered by a nurse in an outpatient clinic. Future research should focus on this issue, because the reasons underlying patient unwillingness to self-administer is key to improving treatment outcomes in the long-term.

Nowadays, the doctor — patient relationship inclines more toward a balanced partnership and shared decision making: physicians are expected to consider patients' preferences and their influence on adherence to therapy [12, 20]. The authors of the aforementioned LEAD study reasoned that patient preference might

correlate with improved adherence to treatment. Although our study did not assess adherence, research in other fields has clearly shown a notable relationship between patient adherence and success of treatment [21]. This is of considerable importance given the chronic nature of acromegaly: it is a disease associated with significant comorbidities, and demands long-term treatment, typically with SSAs. When considering disease management and treatment plans, it is therefore critical to consider, both the potential success of the treatment (relative to the likelihood of adherence) and patient QoL. As stated by Adelman et al., it is important to consider the impact of the treatment on the patient's QoL, just as much as the disease. Despite this understanding, improving patient QoL can be difficult [22], and discordant results have been reported in the literature. For example, in the LEAD study, the results of the AcroQoL questionnaire showed that patients perceived the change of treatment to have no effect on their QoL. On the other hand, recently published data from the PRIMARYS study demonstrated that 48 weeks of treatment with lanreotide Autogel resulted in an improvement in both subjective perception of signs and symptoms as measured by the PASQ and QoL as assessed by the AcroQoL [23]. Treatment naivety could be one of explanations of such discrepancies: patients in the LEAD study were previously treated with octreotide, and patients in the PRIMARYS study were treatment naïve. Furthermore, the latter patients were homogenous with regard to the type of pituitary tumour, since all had macroadenoma with diameter ≥ 10 mm. We observed in our study that the change from octreotide to lanreotide Autogel significantly increased patient satisfaction. Although this raises issues related to perceived and actual benefit, it does highlight that patient preference, likelihood of adherence to treatment, and success of treatment should be considered during acromegaly management.

Our study population encompassed approximately 20% of all patients treated with SSAs in Poland; however, we acknowledge that the main limitation of our study is the generalisation of the findings. We considered whether our patients were representative, in the context of previously published studies, and found demographic characteristics from another multicentre Polish Lanro-Study to be similar to our own. Specifically, the mean ages were 51.7 years (Lanro-Study) vs. 53.7 years (this study), and the percentage of women 70.5% (Lanro-Study) vs. 59.3% (this study). We also found the treatment history of these two groups to be similar: 75% underwent pituitary surgery in the Lanro-Study vs. 74% in the current study. In addition, the mean time since last pituitary surgery was also similar: 7.7 years (Lanro-Study) vs. 7.9 years (this study) [24]. Although

this is a single comparison, we assume our results can be extrapolated to accurately represent the Polish population who currently suffer from acromegaly. An additional limitation of our study is its observational nature with retrospective control data.

Conclusions

Therapy with lanreotide Autogel is related to higher levels of patient satisfaction with acromegaly management, when compared to a previously used SSA (in this case, octreotide). We conclude that this, in turn, may translate to patient treatment preferences. This preference is important for physician consideration when administering a novel treatment and the likelihood of patient adherence. Our findings indicate that the control of acromegaly-specific symptoms was improved as a result of treatment with the new lanreotide device, and this tool addresses certain technical problems associated with SSA injections. Despite the positive effects of the treatment, we did not observe any direct influence on rates of self-administration of lanreotide. Uncovering the underlying reasons preventing patients from self-administering is the key to further improvement of QoL in these patients in the longer term.

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