Lanreotide depot/autogel vs. octreotide LAR for patients with advanced gastroenteropancreatic neuroendocrine tumors: an observational time and motion analysis

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BACKGROUND

- Gastroenteropancreatic neuroendocrine tumors (GEP-NETs) are a group of rare but diverse neoplasms that typically present in the pancreas, stomach, large and small bowel, or rectum.[1]
- Somatostatin analogs (SSAs) are recommended as a treatment option in patients with locally advanced or metastatic GEP-NETs.[2]
- Although the 2 approved long-acting SSAs (lanreotide depot/autogel and octreotide LAR) are recommended in the guidelines for patients with advanced or metastatic GEP-NETs,[2] other product attributes such as drug delivery and preparation time should be considered in overall medical decision making.
- To compare product attributes and overall healthcare operating efficiency, an observational non-randomized time and motion study was undertaken in 5 US cancer centers.

STUDY HYPOTHESIS

- Patients with advanced GEP-NETs often receive SSAs as initial therapy. However, lanreotide depot/autogel has product attributes that may offer practical advantages by facilitating drug preparation, delivery, and overall operating efficiency.

OBJECTIVES

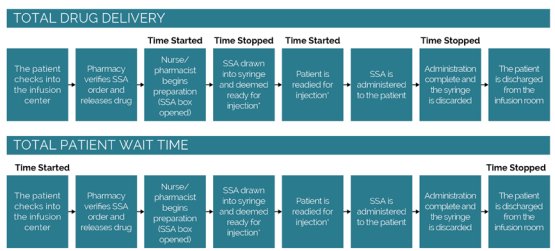
- To compare total drug delivery time between lanreotide depot/autogel and octreotide LAR
- To compare total patient wait time for administration between lanreotide depot/autogel and octreotide LAR
- To measure clinician satisfaction and product preferences
- To assess patient satisfaction

METHODS

Study design

- This was a prospective, non-randomized, non-interventional study consisting of patients with GEP-NETs who were receiving lanreotide depot/autogel or octreotide LAR for the treatment of advanced disease.
- The study used a time and motion design to compare drug delivery attributes between lanreotide depot/autogel and octreotide LAR in patients with advanced GEP-NETs.
- Clinicians were observed and timed throughout the SSA preparation and administration process as outlined in **Figure 1**.

Figure 1. Timing assessments for total drug delivery and total patient wait time throughout the SSA treatment observation



SSA, somatostatin analog.
*Note: if there is overlap between preparing the patient for their injection and SSA preparation, the time the administration started and preparation of the SSA ended should be noted on the CRF.

Outcomes

- Total drug delivery time encompassed the time from when the package/box was opened to begin drug preparation through preparation, as well as administration to the patient.
- Total patient wait time for administration included the time from when the patient checked in at the infusion room until completion of drug administration and discharge of the patient from the infusion room.
- Pharmacist and nurse satisfaction and product preferences, as well as patient satisfaction, were captured at the end of the observation via quantitative and qualitative questionnaires to further understand the treatment experience.

Sample size and statistical considerations

- 22 patients per arm would provide the study with 80% power to detect a difference of 2.0 minutes in total drug delivery time between groups.
- Total time for drug delivery was compared using parametric and non-parametric univariate statistics where appropriate.
- A main effects multilevel regression analysis was also undertaken on the primary and secondary time-related endpoints, with an adjustment for patient clustering.

RESULTS

- A total of 44 patients (octreotide LAR, N=22; lanreotide depot/autogel, N=22) were observed during the study (**Table 1**).
- **Table 2** describes the characteristics of prior and current SSA therapy for the included patients.

Table 1. Baseline patient demographics and treatment characteristics

	Lanreotide Depot/ Autogel N=22	Octreotide LAR N=22
Age (years), mean (range)	64.1 (37–89)	68.3 (40–87)
Male gender, n (%)	11 (50%)	10 (45.4%)
Weight (kg), mean (range)	80 (55–139)	88.0 (43–182)
Disease grade		
I	6 (27.3%)	9 (40.9%)
II	6 (27.3%)	9 (40.9%)
Missing	10 (45.4%)	4 (18.2%)
Primary tumor resected, n (%)	5 (22.7%)	8 (36.4%)
Origin of tumor, n (%)		
Pancreas	3 (13.6%)	5 (22.7%)
Midgut	5 (22.7%)	9 (40.9%)
Hindgut	9 (40.9%)	2 (9.1%)
Other	5 (22.7%)	6 (27.3%)
Disease duration (months), median (range)	6.0 (0.4–123.0)	40.0 (0.5–234.0)
ECOG performance status, n (%)		
0	18 (81.8%)	13 (59.1%)
I	4 (18.2%)	7 (31.8%)
II	0	2 (9.1%)

ECOG, Eastern Cooperative Oncology Group.

Table 2. Characteristics of prior and current SSA therapy

	Lanreotide Depot/ Autogel N=22	Octreotide LAR N=22	*p*-value
Prior treatment for GEP-NETs, n (%)	14 (63.6%)	8 (36.4%)	0.070[a]
Prior treatments, n (%)			
Lanreotide depot/autogel	0	3 (14.3%)	
Octreotide LAR	13 (59.1%)	0	
Everolimus	1 (4.5%)	0	
Chemotherapy	0	2 (9.5%)	
Targeted radiation	0	2 (9.5%)	
None	8 (36.4%)	14 (66.7%)	
Missing	0	1 (4.5%)	
Switched to alternative SSA, n (%)			0.002[a]
Yes	13 (59.1%)	3 (14.3%)	
No	9 (40.9%)	18 (85.7%)	
Missing	0	1 (4.5%)	
Reason for switch, n (%)			
Drug intolerance	2 (9.1%)	2 (9.5%)	
Physician choice	4 (18.2%)	0	
Patient wish	1 (4.5%)	0	
Unknown	6 (27.3%)	0	
Other	0	1 (4.5%)	
Current SSA dose, median (range)	120 (60–120)	30 (10–30)	
Frequency of dose, n (%)			
Every 4 weeks	20 (90.9%)	20 (90.9%)	
Every 3 weeks	2 (9.1%)	2 (9.1%)	
Number of prior SSA doses, median (range)	14.5 (1–72)	20 (1–213)	0.219[b]

[a]Determined using the chi-squared test. [b]Determined using the Mann Whitney U test. GEP-NET, gastroenteropancreatic neuroendocrine tumor; SSA, somatostatin analog.

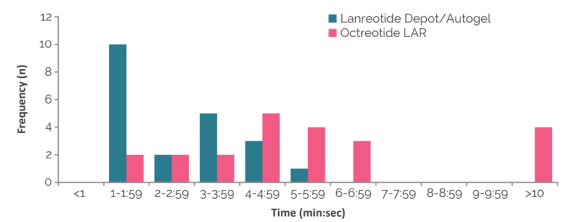
- When the primary study endpoint (total drug delivery time) was compared between groups, there was a mean reduction of 3.7 minutes in favor of lanreotide depot/autogel (2.5 [95%CI: 2.0, 3.1] vs. 6.2 minutes [95%CI: 4.4, 7.9]; $p=0.001$) (**Table 3**; **Figure 2**).
- Total patient wait time (from check-in to checkout) was numerically superior for lanreotide depot/autogel compared with octreotide LAR (32.1 vs. 36.6 minutes), though the comparison failed to reach statistical significance as a high variability was observed in these data (**Table 3**).

Table 3. Resource use and time impact on clinical staff and on the patient

	Lanreotide Depot/ Autogel N=22	Octreotide LAR N=22	*p*-value
Who prepared the drug, n (%)			0.12[a]
Nurse	19 (86.4%)	15 (68.2%)	
Physician	1 (4.6%)	0	
Medical assistant	2 (9.1%)	7 (31.8%)	
Where the dose was prepared, n (%)			0.003[a]
Pharmacy	0	5 (22.7%)	
Medication room	14 (63.6%)	3 (13.6%)	
Bedside	6 (27.3%)	10 (45.4%)	
Other	2 (9.1%)	4 (18.2%)	
Preparation time (minutes)			<0.001[b]
N	21	22	
Median	1.0	3.9	
Mean (SD)	1.38 (0.86)	5.0 (4.00)	
Who administered the drug, n (%)			0.066[a]
Nurse	19 (86.4%)	13 (61.9%)	
Medical assistant	3 (13.6%)	8 (38.1%)	
Missing	0	1 (4.6%)	
Administration time (minutes)			0.869[b]
N	22	22	
Median	1.0	1.1	
Mean (SD)	1.25 (0.59)	1.24 (0.74)	
Total time for drug delivery (minutes)			0.001
N	21	22	
Median	2.0	5.0	
Mean (SD)	2.5 (1.19)	6.2 (4.00)	
Total patient wait time (minutes; from check-in to checkout)			0.734[b]
N	21	22	
Median	25.0	31.2	
Mean (SD)	32.1 (21.4)	36.6 (21.2)	

[a]Determined using the chi-squared test. [b]Determined using the Mann Whitney U test. SD, standard deviation.

Figure 2. Distribution of drug delivery time by drug



Data was missing for 1 lanreotide depot/autogel patient.

- Results from the regression model confirm the total drug delivery time difference found between lanreotide depot/autogel and octreotide LAR while adjusting for potential confounding factors (**Table 4**).

Table 4. Multilevel mixed regression analysis on total drug delivery time and total patient wait time from check-in to checkout

	Mean difference in Log time (min)[a]	95% CI	*p*-value
Total drug delivery time[c,d]			
Lanreotide depot/autogel vs. octreotide LAR	0.42	0.073, 0.772	0.018
Disease duration (years)	-0.03	-0.063, -0.004	0.024
Tumor origin (vs. pancreas)			
Midgut	-0.39	-0.781, -0.002	0.048
Hindgut	-0.23	-0.756, 0.288	0.379
Other	-0.31	-0.829, 0.22	0.215
Constant	1.37	0.692, 2.05	<0.001
Total patient wait time[c,d]			
Lanreotide depot/autogel vs. octreotide LAR	0.016	-0.271, 0.302	0.915
ECOG performance status			
1 (vs. 0)	0.292	0.014, 0.570	0.040
2 (vs. 0)	0.073	-0.051, 0.658	0.806
Constant	3.35	2.621, 4.075	<0.001

[a]To convert the mean difference from log into natural units, the exponential of the point estimate needs to be applied. [b]Dependent variable: Log of drug delivery time. [c]The random effects consisted of the variables "Hospital," "Where Prepared," and "Who Prepared." [d]Dependent variable: Log of total time from patient check in to check out. CI, confidence interval; ECOG, Eastern Cooperative Oncology Group.

- Overall, 20 lanreotide depot/autogel patients (90.9%) reported that all or most of their expectations had been met compared with 18 octreotide LAR patients (81.8%; $p=0.25$) (**Table 5**).
- Based on qualitative data, clinical staff involved in drug administration indicated a preference for lanreotide depot/autogel related to concerns with the longer time to prepare octreotide LAR as well as the increased risk of needle clogging ($p=0.034$) and device failures ($p=0.057$).
- Overall, clinicians involved in preparing and delivering SSAs indicated significantly higher satisfaction with lanreotide depot/autogel than octreotide LAR (median satisfaction score = 5 vs. 4; $p=0.006$).

Table 5. Post-drug administration questionnaire to patients

	Lanreotide Depot/ Autogel N=22	Octreotide LAR N=22	*p*-value
Treatment expectations, median rank (range)[a]			
Control the spread of cancer	1 (1–6)	1 (1–6)	
Control of symptoms	2 (1–6)	2 (1–6)	
Free from drug side effects	4 (1–6)	3 (1–6)	
Easy and pain free drug injection	5 (1–6)	4 (1–6)	
Covered by insurance company	3 (1–6)	4.5 (1–6)	
Expectations met by current drug therapy, n (%)			
All have been met	12 (54.6%)	15 (71.4%)	0.255[b]
Most have been met	8 (36.4%)	3 (14.3%)	
Some not met	2 (9.1%)	3 (14.3%)	
Expectations not met, n (%)			
Control the spread of cancer	8 (36.4%)	7 (31.8%)	
Control of symptoms	2 (9.1%)	4 (18.2%)	
Drug side effects	4 (18.2%)	2 (9.1%)	
Drug injection not quick and easy	1 (4.5%)	2 (9.1%)	
Drug injection painful	3 (13.6%)	2 (9.1%)	
Advantages of current drug therapy, median rank (range)[c]			
Drug is controlling my cancer	1 (1–7)	1 (1–7)	
The drug is controlling the cancer symptoms	2 (1–7)	3 (1–7)	
Very few side effects	3 (1–7)	3 (1–7)	
Convenient	3.5 (1–7)	3 (1–7)	
The drug is improving my quality of life	3.5 (1–7)	6 (1–7)	
Drug is making me feel better	4 (1–7)	4 (1–7)	
Injection not too painful	5 (1–7)	4 (1–7)	
Dislikes about current therapy, median (range)[d]			
Inconvenient	1 (1–6)	2.5 (1–6)	0.544[e]
Too many side effects	3 (1–6)	3.5 (1–6)	0.058[e]
The injection is too painful	2 (1–6)	1 (1–6)	0.666[e]
Would you recommend the drug to others?, n (%)			
Yes	21 (95.4%)	22 (100%)	
No	1 (4.6%)	0	
Would you switch to another drug if available?, n (%)			
No	9 (40.9%)	10 (45.4%)	0.544[b]
Possibly	13 (59.1%)	11 (50.0%)	
Yes	0	1 (4.6%)	
Level of satisfaction[f]			
Median (range)	4.8 (3–5)	4.6 (2.5–5)	0.689[e]
How well are you feeling today?[g]			
Median (range)	3.1 (0–10)	3.1 (0–9)	0.850[e]

[a]Rated on a scale from 1 (expectations fully met) to 6 (expectations not met). [b]Determined using the chi-squared test. [c]Rated on a scale from 1 (total advantage) to 7 (no advantage). [d]Rated on a scale from 1 (hate) to 6 (love). [e]Determined using the Mann Whitney U test. [f]Rated on a scale from 1 (not all satisfied) to 5 (very satisfied). [g]Rated on a scale from 1 (great) to 10 (terrible).

Exploratory sensitivity analysis

- Adjustment for the treatment center effect found a 13.5-minute difference in total patient wait time favoring lanreotide depot/autogel (octreotide LAR=45.6 min, lanreotide depot/autogel = 32.1 min; $p=0.0573$) when excluding 1 community oncology center (n=6 octreotide LAR observations).

Limitations

- Patients in each group were not randomly allocated.
- Overall, 13 lanreotide depot/autogel patients (59.1%) received prior octreotide LAR that was subsequently switched. In contrast, only 3 octreotide LAR patients (13.6%) had prior lanreotide depot/autogel exposure that required switching ($p=0.002$).
- Multiple statistical comparisons were performed, without an adjustment for multiplicity.
- The sample size was obtained from only 5 centers (convenience sample), which limits the generalizability of the findings.

CONCLUSIONS

- Lanreotide depot/autogel resulted in statistically significant reductions in pharmacy and nurse time for drug delivery compared to octreotide LAR.
- Lanreotide depot/autogel was preferred by nurses involved in drug preparation and administration because it was the most comfortable and safe to use and it reduced the stress associated with needle clogging and device failures.
- Overall, lanreotide depot/autogel provided greater confidence to nurses in the care of their patients.

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Conflicts of interest

PR: stock/other ownership options in Advanced Accelerator Applications; honoraria from Ipsen and Lexicon; consultant/advisor for Ipsen and Lexicon; member of speaker's bureau for Ipsen. **DR:** employee of Ipsen. **SJP:** employee of Ipsen; stock/other ownership options in Ipsen and Johnson & Johnson; research funding from Ipsen. **RAR:** immediate family member with stock/other ownership options in Advanced Accelerator Applications; consultant/advisor for Novartis and Advanced Accelerator Applications; member of speaker's bureau for Ipsen, Merck, Genentech, AstraZeneca, and Guardant Health. **JPF:** consultant/advisor for Amgen; research funding from Novartis and Pfizer. **GD:** leadership at, honoraria from, consultant/advisor for, and research funding from Ipsen. **AM** and **EE:** nothing to declare.

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- Gastroenteropancreatic neuroendocrine tumors (GEP-NETs) are a group of rare but diverse neoplasms that typically present in the pancreas, stomach, large and small bowel, or rectum.[1]
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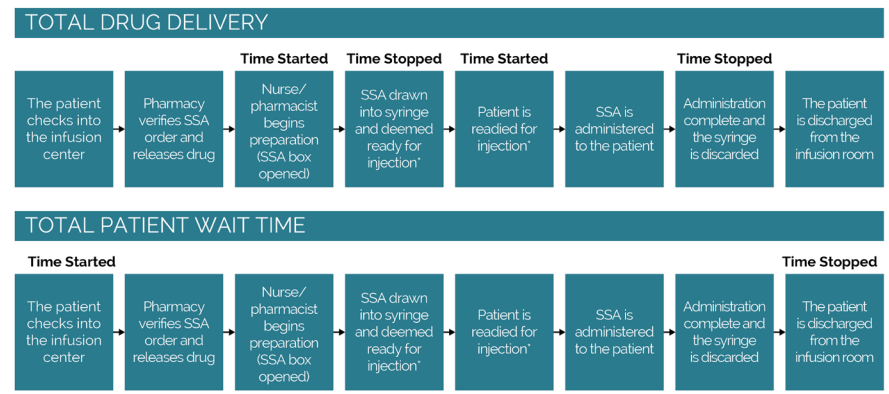

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- **Table 2** describes the characteristics of prior and current SSA therapy for the included patients.

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Switched to alternative SSA, n (%)			0.002[a]
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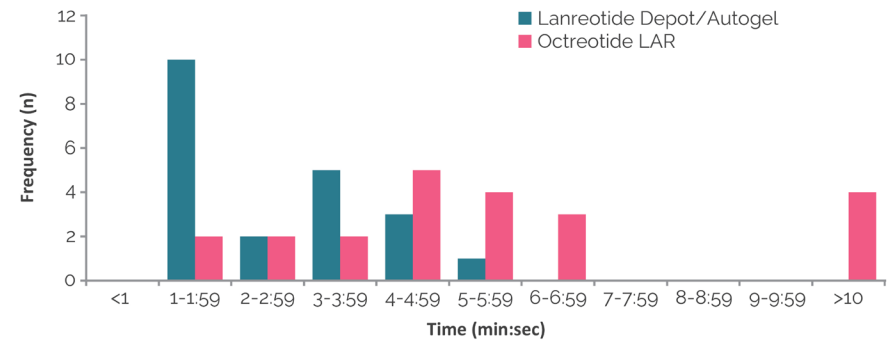
Medical assistant	2 (9.1%)	7 (31.8%)	
Where the dose was prepared, n (%)			0.003[a]
Pharmacy	0	5 (22.7%)	
Medication room	14 (63.6%)	3 (13.6%)	
Bedside	6 (27.3%)	10 (45.4%)	
Other	2 (9.1%)	4 (18.2%)	
Preparation time (minutes)			<0.001[b]
N	21	22	
Median	1.0	3.9	
Mean (SD)	1.38 (0.86)	5.0 (4.00)	
Who administered the drug, n (%)			0.066[a]
Nurse	19 (86.4%)	13 (61.9%)	
Medical assistant	3 (13.6%)	8 (38.1%)	
Missing	0	1 (4.6%)	
Administration time (minutes)			0.869[b]
N	22	22	
Median	1.0	1.1	
Mean (SD)	1.25 (0.59)	1.24 (0.74)	
Total time for drug delivery (minutes)			0.001
N	21	22	
Median	2.0	5.0	
Mean (SD)	2.5 (1.19)	6.2 (4.00)	
Total patient wait time (minutes; from check-in to checkout)			0.734[b]
N	21	22	
Median	25.0	31.2	
Mean (SD)	32.1 (21.4)	36.6 (21.2)	

[a]Determined using the chi-squared test. [b]Determined using the Mann Whitney U test. SD, standard deviation.

Figure 2. Distribution of drug delivery time by drug



Data was missing for 1 lanreotide depot/autogel patient.

- Results from the regression model confirm the total drug delivery time difference found between lanreotide depot/autogel and octreotide LAR while adjusting for potential confounding factors (**Table 4**).

Table 4. Multilevel mixed regression analysis on total drug delivery time and total patient wait time from check-in to checkout

	Mean difference in Log time (min)[a]	95% CI	*p*-value
Total drug delivery time[b,c]			
Lanreotide depot/autogel vs. octreotide LAR	0.42	0.073, 0.772	0.018
Disease duration (years)	-0.03	-0.063, -0.004	0.024
Tumor origin (vs. pancreas)			
Midgut	-0.39	-0.781, -0.002	0.048
Hindgut	-0.23	-0.756, 0.288	0.379
Other	-0.31	-0.829, 0.22	0.215
Constant	1.37	0.692, 2.05	<0.001
Total patient wait time[c,d]			
Lanreotide depot/autogel vs. octreotide LAR	0.016	-0.271, 0.302	0.915
ECOG performance status			
1 (vs. 0)	0.292	0.014, 0.570	0.040
2 (vs. 0)	0.073	-0.051, 0.658	0.806
Constant	3.35	2.621, 4.075	<0.001

[a]To convert the mean difference from log into natural units, the exponential of the point estimate needs to be applied. [b]Dependent variable: Log of drug delivery time. [c]The random effects consisted of the variables "Hospital," "Where Prepared," and "Who Prepared." [d]Dependent variable: Log of total time from patient check in to check out. CI, confidence interval; ECOG, Eastern Cooperative Oncology Group..

Lanreotide depot/autogel vs. octreotide LAR for patients with advanced gastroenteropancreatic neuroendocrine tumors: an observational time and motion analysis

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- Overall, 20 lanreotide depot/autogel patients (90.9%) reported that all or most of their expectations had been met compared with 18 octreotide LAR patients (81.8%; p=0.25) (**Table 5**).
- Based on qualitative data, clinical staff involved in drug administration indicated a preference for lanreotide depot/autogel related to concerns with the longer time to prepare octreotide LAR as well as the increased risk of needle clogging (p=0.034) and device failures (p=0.057).
- Overall, clinicians involved in preparing and delivering SSAs indicated significantly higher satisfaction with lanreotide depot/autogel than octreotide LAR (median satisfaction score = 5 vs. 4; p=0.006).

Table 5. Post-drug administration questionnaire to patients

	Lanreotide Depot/Autogel N=22	Octreotide LAR N=22	*p*-value
Treatment expectations, median rank (range)[a]			
Control the spread of cancer	1 (1–6)	1 (1–6)	
Control of symptoms	2 (1–6)	2 (1–6)	
Free from drug side effects	4 (1–6)	3 (1–6)	
Easy and pain free drug injection	5 (1–6)	4 (1–6)	
Covered by insurance company	3 (1–6)	4.5 (1–6)	
Expectations met by current drug therapy, n (%)			
All have been met	12 (54.6%)	15 (71.4%)	0.255[b]
Most have been met	8 (36.4%)	3 (14.3%)	
Some not met	2 (9.1%)	3 (14.3%)	
Expectations not met, n (%)			
Control the spread of cancer	8 (36.4%)	7 (31.8%)	
Control of symptoms	2 (9.1%)	4 (18.2%)	
Drug side effects	4 (18.2%)	2 (9.1%)	
Drug injection not quick and easy	1 (4.5%)	2 (9.1%)	
Drug injection painful	3 (13.6%)	2 (9.1%)	
Advantages of current drug therapy, median rank (range)[c]			
Drug is controlling my cancer	1 (1–7)	1 (1–7)	
The drug is controlling the cancer symptoms	2 (1–7)	3 (1–7)	
Very few side effects	3 (1–7)	3 (1–7)	
Convenient	3.5 (1–7)	3 (1–7)	
The drug is improving my quality of life	3.5 (1–7)	6 (1–7)	
Drug is making me feel better	4 (1–7)	4 (1–7)	
Injection not too painful	5 (1–7)	4 (1–7)	
Dislikes about current therapy, median (range)[d]			
Inconvenient	1 (1–6)	2.5 (1–6)	0.544[e]
Too many side effects	3 (1–6)	3.5 (1–6)	0.058[e]
The injection is too painful	2 (1–6)	1 (1–6)	0.666[e]
Would you recommend the drug to others?, n (%)			
Yes	21 (95.4%)	22 (100%)	
No	1 (4.6%)	0	
Would you switch to another drug if available?, n (%)			
No	9 (40.9%)	10 (45.4%)	0.544[b]
Possibly	13 (59.1%)	11 (50.0%)	
Yes	0	1 (4.6%)	
Level of satisfaction[f]			
Median (range)	4.8 (3–5)	4.6 (2.5–5)	0.689[e]
How well are you feeling today?[g]			
Median (range)	3.1 (0–10)	3.1 (0–9)	0.850[e]

[a]Rated on a scale from 1 (expectations fully met) to 6 (expectations not met). [b]Determined using the chi-squared test. [c]Rated on a scale from 1 (total advantage) to 7 (no advantage). [d]Rated on a scale from 1 (hate) to 6 (love). [e]Determined using the Mann Whitney U test. [f]Rated on a scale from 1 (not all satisfied) to 5 (very satisfied). [g]Rated on a scale from 1 (great) to 10 (terrible).

Exploratory sensitivity analysis

- Adjustment for the treatment center effect found a 13.5-minute difference in total patient wait time favoring lanreotide depot/autogel (octreotide LAR=45.6 min, lanreotide depot/autogel = 32.1 min; p=0.0573) when excluding 1 community oncology center (n=6 octreotide LAR observations).

Limitations

- Patients in each group were not randomly allocated.
- Overall, 13 lanreotide depot/autogel patients (59.1%) received prior octreotide LAR that was subsequently switched. In contrast, only 3 octreotide LAR patients (13.6%) had prior lanreotide depot/autogel exposure that required switching (p=0.002).
- Multiple statistical comparisons were performed, without an adjustment for multiplicity.
- The sample size was obtained from only 5 centers (convenience sample), which limits the generalizability of the findings.

CONCLUSIONS

- Lanreotide depot/autogel resulted in statistically significant reductions in pharmacy and nurse time for drug delivery compared to octreotide LAR.
- Lanreotide depot/autogel was preferred by nurses involved in drug preparation and administration because it was the most comfortable and safe to use and it reduced the stress associated with needle clogging and device failures.
- Overall, lanreotide depot/autogel provided greater confidence to nurses in the care of their patients.

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Conflicts of interest

PR: stock/other ownership options in Advanced Accelerator Applications; honoraria from Ipsen and Lexicon; consultant/advisor for Ipsen and Lexicon; member of speaker's bureau for Ipsen. **DR:** employee of Ipsen. **SJP:** employee of Ipsen; stock/other ownership options in Ipsen and Johnson & Johnson; research funding from Ipsen. **RAR:** immediate family member with stock/other ownership options in Advanced Accelerator Applications; consultant/advisor for Novartis and Advanced Accelerator Applications; member of speaker's bureau for Ipsen, Merck, Genentech, AstraZeneca, and Guardant Health. **JPF:** consultant/advisor for Amgen; research funding from Novartis and Pfizer. **GD:** leadership at, honoraria from, consultant/advisor for, and research funding from Ipsen. **AM** and **EE:** nothing to declare.

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