Prevalence of self-reported side effects in neuroendocrine tumour patients prescribed somatostatin analogues

Tara Whyand, Catherine Bouvier and Philippa Davies

ABSTRACT

Somatostatin analogues (SSA) are a common treatment for some forms of neuroendocrine tumours (NETs). Patients report a variety of side effects after starting these drugs, so in most cases they require a lot of nutritional input. The authors used an online survey to invite responses from patients worldwide to determine the extent of reported side effects. Patients were asked which SSA they were taking and how they rated the severity of their side effects. They were provided with a list of 11 options to choose from, but not given any guidance or a definition of terms. The most commonly reported side effect was constipation (85%), with 8.6% of these respondents rating its severity as 10/10. The survey found that many self-reported side effects from the use of SSAs were experienced more frequently than previous clinical studies or the patient information leaflets reported. As this was an online survey, so the findings are limited in that first, this was a self-selected sample of patients and second, patients were able to respond more than once.

Key words: Nutrition Somatostatin analogues Side effects Neuroendocrine tumours

> he main role of a specialist neuroendocrine tumour (NET) dietitian is to help patients manage the side effects of treatment so they do not become underweight, do not become deficient in nutrients, and to enable them to have a good quality of life (QoL) despite adverse bowel problems. In practice, many patients with NETs report a change in symptoms after starting treatment with somatostatin analogues (SSAs). Many health professionals and NET patient advocates have noticed that some of the side effects experienced appear to be more common than the patient information literature suggests.

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Supporting those experiencing side effects of treatment, including SSAs, contributes significantly to the nursing workload. The authors therefore thought it important to investigate the subject by asking patients about the side effects they developed with SSA treatment and the severity of these. The aim was to help raise awareness about the side effects of SSAs among health professionals and patients, and help acknowledge the need for knowledge among dietitians and specialist nurses within NET multidisciplinary teams.

A literature search was conducted; however, because the field of neuroendocrine tumours is a relatively new area of cancer research, there was limited up-to-date literature about SSAs, nutrition and NETs.

Method

A survey created with SurveyMonkey was posted on Twitter, the NET Patient Foundation website and its closed patient support group, which was already established and was open to patients worldwide. It asked them:

- Which somatostatin analogue have you been prescribed?
- Rate the severity on a scale of 0–10 of any side effects experienced. (The 0-10 rating scale was used to ensure clarity and to avoid any confusion.)

Respondents were then provided with a choice of 11 side effects:

- Constipation
- Steatorrhoea
- Diarrhoea
- Feeling the burden of treatment
- Vitamin B₁₂ deficiency
- Hair thinning
- Nausea
- Fat-soluble vitamin deficiency
- Weight loss
- Low glucose level
- Gallstones.

The list was based on the side effects reported by patients to dietitians and nurses specialising in NETs at the Royal Free Hospital and to the NET Patient Foundation. Patients were expected to answer the questions based on their personal experiences. Assumptions were made that, where the side effects warranted, patients had obtained their diagnosis from a health professional. The survey gave no guidance as to how

Table 1. Self-reported side effects from patients after starting on somatostatin analogues: data from online survey and product literature					
Symptom	Number of patients affected (n=176)	% respondents affected (n=176)	Weighted average severity rating (scale of 1–10)	% patients affected on Sandostatin LAR studies [*]	% patients affected on Somatuline Autogel studies [†]
Constipation	150	85.22%	4.26	≥10%	0.1-9.99%
Steatorrhoea	148	84.09%	4.19	0.1–9.99%	0.1-9.99%
Diarrhoea	139	78.97%	3.75	≥10%	≥10%
Feeling the burden of treatment	119	67.61%	2.94	No data	No data
Vitamin B ₁₂ deficiency	110	62.50%	2.97	No data	No data
Hair thinning	101	57.38%	2.34	0.1–9.99%	0.1–9.99%
Nausea	93	52.84%	1.85	≥10%	0.1–9.99%
Vitamin A,D,E,K deficiency	91	51.70%	2.22	No data	No data
Weight loss	76	43.18%	1.72	No data	0.1–9.99%
Low glucose levels	75	42.61%	1.97	0.1–9.99%	0.1–9.99%
Gallstones	29	16.47%	0.76	≥10%	≥10%

* Novartis Pharmaceuticals UK Ltd, 2018 [†] Ipsen Ltd, 2017;

to classify the side effects, e.g. deficiencies, abnormal stools, weight loss percentage or grading of nausea.

Results

There were 172 responses to question 1 regarding brand of SSA. Eighty nine (51.7%) respondents had been prescribed Sandostatin LAR (octreotide), with the remainder (48.3%) Somatuline Autogel (lanreotide).

There were 176 responses to question 2. The most common side effects reported were constipation, steatorrhoea and diarrhoea (*Table 1*). Constipation was reported by 150 patients of the 176, 8.6% of whom gave this a top severity rating of 10/10. Steatorrhoea was the second biggest symptom, with 148 patients reporting it. Diarrhoea was the third most common side effect, with 139 patients affected.

Discussion

Although these international findings of patients' experiences on SSAs make for interesting reading, it is important to note that the presence of other factors may have increased symptoms or caused new ones, and that patients self-reported that these side effects had started once they commenced on SSAs.

Most side effects were reported in higher numbers compared with the figures cited in the SSA patient information literature (Ipsen Ltd, 2017; Novartis Pharmaceuticals UK Ltd, 2018). In addition, the product information for either Sandostatin LAR or Somatuline Autogel does not document 'feeling the burden of treatment', B_{12} deficiency and fatsoluble vitamin deficiency as official side effects or adverse events. Weight loss when being treated with Sandostatin LAR is also not mentioned.

Side effects Constipation

Constipation as a side effect of SSAs is not a well-publicised problem with NETs, but in this survey it was reported by more than 85% of respondents as occurring at some point after starting on SSAs. The Sandostatin LAR product information states that this is a very common side effect (1–10%) (Novartis Pharmaceuticals UK Ltd, 2018), while the Somatuline Autogel product information lists it as a common side effect in up to 10% of patients (Ipsen Ltd, 2017).

While respondents to this survey reported constipation as a problem, the authors have been unable to find any published studies that highlighted this as an issue. Patients need to know how to manage constipation, as well as loose stools, which are most often discussed in connection with SSAs and NETs.

Diarrhoea

No matter what the cause, diarrhoea is a debilitating problem. In this survey, 78% of people reported having it while on treatment with SSAs. Diarrhoea is described as a very common adverse event in the product information for both Sandostatin LAR (Novartis Pharmaceuticals UK Ltd, 2018) and Somatuline Autogel (Ipsen Ltd, 2017), each stating that it affects 10% of patients or more.

Loose stools are often reported as diarrhoea, and for some patients there may be a degree of steatorrhoea too. There is often more than one cause of loose stools, i.e. active tumours, carcinoid triggers, surgery, small intestinal bacterial overgrowth and/or bile acid malabsorption. It is therefore important that patients discuss their type of stool with the medical and nursing teams, so that appropriate investigations and therapies, including an appointment with a dietitian, can be arranged where necessary.

Pancreatic enzymes, steatorrhoea and fat-soluble vitamins

Pancreatic enzyme insufficiency is one cause of fat loss in stools. When the fat is obvious, it causes greasy and frothy loose stools called steatorrhoea. Among the survey respondents, 84% stated they had this to varying degrees. The SSA octreotide is able to inhibit plasma amino acid uptake by pancreatic acinar cells and, consequently, the synthesis of pancreatic enzymes (Gullo et al, 1991). Somatuline Autogel product information states that a pool of studies in gastroenteropancreatic NETs found that decreasing pancreatic enzymes was a common problem ($\geq 10\%$) (Ipsen Ltd, 2017).

In published studies, steatorrhoea was an adverse effect experienced by up to 29% of patients on SSA treatment (Shah and Caplin, 2005). Fiebrich et al (2010) also noted that it was obvious in 23% of patients on SSAs. However, steatorrhoea does not have to be visible to cause nutritional malabsorption and it does not always correlate to the degree of pancreatic enzyme insufficiency, if measured. Steatorrhoea should therefore not be used as an indication of the need for pancreatic enzyme replacement therapy (PERT) (Bartel et al, 2015).

In the past, stools have been tested for fat and faecal elastase, but there appears to be a lack of association between faecal elastase and steatorrhoea in patients with NETs (Chaudhry et al, 2016). Many patients experience steatorrhoea while on treatment with SSAs, despite normal faecal elastase—it should therefore not be used to evaluate pancreatic function in NET patients (Chaudhry et al, 2016). This points to the need for a clear pathway to investigate loose stools, which must include in-depth history taking of stool type, colour, frequency and any dietary triggers.

Vitamin deficiencies cause a wide variety of health problems, ranging from night blindness and osteoporosis to bleeding and dry skin. In this study, 51% of patients reported some form of fat-soluble vitamin deficiency. Lind et al (2016) found that vitamin D deficiency was common (29% severe; 17% moderate) in a control group of 25 patients with small intestinal NETs, but supplementation of vitamin D in the intervention group of 25 patients appeared to have prevented severe deficiency completely. Fiebrich et al (2010) found that 78% (n=42) of NET and acromegaly patients on SSAs were deficient in one or more vitamins, with 32% (n=17) having multiple deficiencies. Deficiencies for vitamin A, D, E, K₁ and E in erythrocytes occurred in 6%, 28%, 15%, 63% and 58% of patients respectively. Prevalence of vitamin D, E and K1 deficiencies was similar in the acromegaly and serotoninproducing NET patient groups in the Fiebrich et al (2010) study. It is important to note that SSA treatment duration did not affect vitamin levels and therefore deficiencies can develop quickly after treatment commences, perhaps more so in patients with lower baseline levels.

SSAs are, however, unlikely to be the sole cause of vitamin deficiencies in NET patients. The frequent resection of a

part of the small intestine, as performed in mid-gut NET patients, could be an additional reason for malabsorption. The severity of malabsorption after an intestinal resection depends on the total remaining digestive surface area and portion of small intestine. Patients who have undergone a partial small-bowel resection may therefore be at greater risk of developing vitamin deficiency than NET or acromegaly patients without bowel resection (Kastin and Buchman, 2002).

Patients with a <200 cm residual bowel after resection run the highest risk of developing deficiencies. The guidelines of both the British Society of Gastroenterology (Nightingale et al, 2006) and American Gastroenterology Association (2003) state that fat-soluble vitamins may need to be supplemented if <200 cm of short bowel remains after resection, but neither suggests a specific screening regimen.

The latest ESPEN guidelines on chronic intestinal failure (Pironi et al, 2016) strongly recommend that baseline serum vitamin concentrations are measured according to laboratory availability at the onset of home parenteral nutrition (HPN), then at least once a year. The guidelines discuss fat-soluble vitamins in detail with regard to home parenteral nutrition (Pironi et al, 2016). Early studies in small numbers of patients who had had resection of varying lengths of intestine showed that resection of more than 100 cm of the terminal ileum leads to insufficient intra-intestinal bile salt concentrations, which might in turn lead to steatorrhoea and fat-soluble vitamin malabsorption (Booth et al, 1961; Aldini et al, 1992). However, existing guidelines provide unclear advice on the management of ileal resections. Fiebrich et al (2010) found that bowel resection influenced plasma levels of vitamin A, but interestingly not the plasma levels of other fat-soluble vitamins.

Studies of healthy humans' intestinal perfusion have shown that SSAs interfere with the absorption of nutrients (Lamrani et al, 1997). Commencing on SSAs significantly decreases duodenal absorption of carbohydrates and triglycerides (Lamrani et al 1997) so, in addition to reducing pancreatic enzyme secretion and thus causing pancreatic enzyme insufficiency, SSAs may directly reduce absorption and cause vitamin deficiencies in this patient group too. It may also explain why many NET patients suffer with small intestinal bacterial overgrowth: macronutrients can act as a food source when not digested further up the gastrointestinal tract. It is therefore important to make patients aware of probable adverse events and monitor them actively for the likely side effects of treatment and surgery.

Vitamin B12 deficiency

A study by Plöckinger et al (1990) found that all patients had a decline in vitamin B_{12} from baseline within 2 years of starting treatment with SSAs. Studies for the product manufacturers on the tolerability of Somatuline Autogel did not test for this deficiency (Ipsen Ltd, 2017), however the Sandostatin LAR information (Novartis Pharmaceuticals UK Ltd, 2018) carries the following warning: 'Depressed vitamin B_{12} levels and abnormal Schilling's tests have been observed in some patients receiving octreotide therapy. Monitoring of vitamin B_{12} levels is recommended during therapy with Sandostatin LAR in patients who have a history of vitamin B12 deprivation' (Novartis Pharmaceuticals UK Ltd, 2018).

In this study, more than 62% of patients reported that they experienced vitamin B_{12} deficiency after starting SSA treatment. This could have been due to extensive disease or surgery to the stomach/ileum, factors that may also lead to deficiency and are common in small intestinal NETs (Lind et al, 2016). This study also found that patients who were supplemented with B_{12} as standard did not become deficient (Lind et al, 2016). It would therefore seem advisable to monitor vitamin B_{12} levels in most NET patients.

Gallstones

Gallstones, which are usually asymptomatic (Redfern and Fortuner, 1995), occur in 10–50% of patients treated with SSAs (Trendle et al, 1997; Oberg et al, 2004; Melmed, 2009). Plöckinger et al (1990) found that 60% of patients with acromegaly developed new gallstones within 2 years of starting treatment with SSAs.

This survey found that gallstones were less common than previously reported, with only a 16% incidence. Interestingly, the Sandostatin LAR and Somatuline Autogel studies found gallstones to be a very common (10% or more) adverse event (Ipsen Ltd, 2017; Novartis Pharmaceuticals UK Ltd, 2018). This difference may be explained by most patients not suffering with any noticeable gallstone symptoms, so they go undetected if not picked up on scans, and the gallbladder is commonly removed.

Weight loss

Weight is often seen as a reflection of health status, with underweight patients often struggling to carry on working and undertaking daily activities. A study in patients with abdominal NETs found malnutrition to be associated with a nearly fivefold higher risk of inpatient mortality (Glazer et al, 2014). A UK study of 161 gastroenteropancreatic NET patients found that those at high risk of malnutrition were more likely to be on somatostatin analogues treatment (Qureshi et al, 2016). The most recent study of malnutrition in NET patients found that 38% were at nutritional risk, and this was more frequent in those with residual disease (Borre et al, 2018). The study found that 12% of patients had a body mass index of under 20.5 kg/m², but that 43% had an impaired level of function.

In this survey, 43% of patients indicated that they were affected by some level of weight loss. Malnutrition screening should be in place to enable referrals to specialist NET dietitians, although there is as yet no validated screening tool specific to NETs. Weight decrease is noted as a common (1-10%) effect of Somatuline Autogel (Ipsen Ltd, 2017), however was not found for Sandostatin LAR (Novartis Pharmaceuticals UK Ltd, 2018).

Hair thinning

Hair thinning, or alopecia, appears to be a common side effect, with 57% of patients in this survey noting this to some degree. This is much more than that rated common (1–10%)

in the SSA product information (Ipsen Ltd, 2017; Novartis Pharmaceuticals UK Ltd, 2018). Hair loss is linked to some vitamin and mineral deficiencies, especially biotin and iron (Rushton, 2002), however, to the authors' knowledge, these have not been measured in any SSA trials. Theoretically, it is possible that vitamins and minerals, even those that are water soluble, may be malabsorbed when a patient experiences loose stools or diarrhoea. Evidence-based information on how to treat thinning hair needs to be made more widely available to staff and patients because, according to the responses to the survey, this seems to occur more frequently than first thought.

Nausea

Nausea can be debilitating, affecting patients' QoL as well as their nutritional intake. Data on nausea vary from very common ($\geq 10\%$) (Novartis Pharmaceuticals UK Ltd, 2018) to common (0.1–9.99%) (Ipsen Ltd, 2017), but 53% of respondents to this survey reported nausea. Nausea has also been associated with hand-grip strength and nutritional risk in NET patients (Borre et al, 2018).

Resources on how to manage nausea are widely available, but patients may need to be made aware of where to access to help them improve nutritional intake and prevent malnutrition.

Hypoglycaemia

Low glucose levels can cause light headedness and cause patients to faint. There is no official recommendation on testing glucose levels after starting SSAs. Hypoglycaemia was reported in the survey in far higher numbers (43%) than in the manufacturers' product information, which lists hypoglycaemia as common, but at 1–10% (Ipsen Ltd, 2017; Novartis Pharmaceuticals UK Ltd, 2018). However, because this is a self-reported survey, patients may have had an actual diagnosis or just have a perception of having deranged blood sugar levels. Research needs to be undertaken to determine the best ways to monitor patients.

Feeling the burden of treatment

Ongoing treatment for any disease is likely to affect how a patient feels. In this study, more than two thirds (67%) considered the side effects of SSAs to be a burden on their life. QoL data and adverse event reporting for patients on all treatment is important, so that the specialist team can provide supportive tools to manage any adverse events. Surprisingly, there was no QoL data for patients on SSAs in the literature search and this is an area that requires further research.

Limitations of the study

The data presented here reflect what patients report and are based on what they perceive to be symptoms linked to the use of SSAs. The data may not be completely accurate because this was a self-selecting sample of patients and because they were able to respond more than once. The number of respondents was relatively low and may reflect the perception of those who felt most strongly about reporting their symptoms. Those with fewer or no symptoms may have chosen not to complete the survey.

Conclusion

The survey collected information on the patient experience data after prescription of SSAs. It is clear that consultations should include more direct questions, because patients may not report adverse events without direct prompts. Most selfreported side effects due to SSA treatment appear to be more frequent than suggested by the clinical trial data that underpins the advice in the product information, although use of this medication is not the only reason these symptoms can occur during a NET patient's pathway. It is also important to note that the survey reflects the data from patients who have been on SSAs for much longer than most patients in previous SSA clinical trials.

Patients need to be made aware of possible adverse events not mentioned in the medication information leaflets and be provided with more information about how to treat these. SSAs may affect absorption directly in the duodenum and through disabling pancreatic enzyme formation.

Because side effects or adverse events from SSAs are very common, they must be reported to the pharmaceutical company by the health professional, or patients can report side effects directly via the Yellow Card Scheme (www.mhra. gov.uk/yellowcard).

To prevent weight loss and nutrient deficiencies, we recommend routine assessment of fat-soluble vitamins in patients on SSAs, especially those with an intestinal resection. Pancreatic enzyme replacement therapy is often required.

Vitamin B_{12} should also be tested in patients on SSAs, even if the patient does not have an ileal or gastric NET, or surgery to these organs. The patient and monitoring NET units must both know how much intestine has been removed in any surgery to enable proper surveillance. Vitamin supplementation should be initiated when symptoms are present or to prevent complications. Specialist NET dietitians are critical to any NET unit in helping prevent, treat and manage a patient's deficiencies and treatment side effects over the person's lifetime. **BJN**

Conflict of interest: none

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KEY POINTS

- Neuroendocrine tumour multidisciplinary (NET) teams should include at least one NET specialist dietitian
- Stool frequency, consistency and colour must be recorded at every NET appointment to help the patient distinguish between diarrhoea and steatorrhoea. Loose stools and constipation warrant investigation
- Patients must be screened for malnutrition during all hospital visits
- Fat-soluble vitamins need to be checked before starting somatostatin analogues (SSAs), ideally every 6–12 months.
- Test for small intestinal bacterial overgrowth and bile-acid malabsorption in patients who have diarrhoea or steatorrhoea that has not resolved with antidiarrhoeals, enzymes or dietary changes
- Vitamin B₁₂ levels should be monitored every 6–12 months in patients prescribed SSAs, who have had stomach/ileal surgery and in cases where there may be sufficient disease to cause malabsorption
- Random blood glucose testing should be considered after SSA prescription
- Patients should be asked how they are managing with treatment, specifically direct questions about possible side effects, face to face or in a quality of life questionnaire. Offer counselling, if the burden of treatment is too much
- Resources need to be made available to help patients manage possible adverse events/side effects

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- **CPD** reflective questions
- What improvements can you make to your care of patients on SSA?
- Can you implement nutritional screening in your setting?
- How often do you report adverse events from SSA or other medications?

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