Hypersensitivity reactions in the home parenteral nutrition patient after initiation or change to injectable lipid emulsion product

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Background

The ability to initiate or change the lipid injectable emulsion (ILE) component of home parenteral nutrition (HPN) is important for quality clinical care and product supply chain interruptions due to shortages. ILE products are derived from potential allergens, including egg, soy and/or fish. ILE hypersensitivities, although rare, add a layer of clinical complexity when attempting to safely implement changes to the HPN formula.

Purpose

The objective of this quality improvement project was to provide a descriptive analysis of hypersensitivity reactions in HPN patients receiving ILE to better understand the prevalence of these reactions in the home setting.

Methods

- This project occurred between 3/1/21-12/20/21, during a time of many national shortages of ILE products, requiring frequent changes to the HPN formula
- Demographic and clinical information, including any reported hypersensitivity reactions were recorded and summarized. The data collected about ILE product type and dose, as well as the presence and severity of any hypersensitivity reaction were retrospectively analyzed.
  - **Inclusion criteria:**
    - HPN patients with no known lifetime use of the oil source within the newly prescribed ILE product
    - Home nurse present during the infusion
  - **Exclusion criteria:**
    - History of severe atopic reaction to the ILE product or oil source, requiring hospitalization for the first dose

Results

- Data from 96 patients met criteria for the analysis
- 74% (n=71) of patients were changed from soy oil-based ILE (SO-ILE) to another ILE type
  - Of these patients, most had no change to their total dose of ILE grams per week (66.7%, n=64), whereas only 5.2% (n=5) decreased and 2.1% (n=2) increased
  - 26%(n=25) were naïve to all ILE types
  - The most frequently introduced ILE type was olive, soy oil-based ILE (OO,SO-ILE) (56%, n=54), followed by soy, medium chain triglycerides (MCT), olive, fish oil-based ILE (SO, MCT, OO, FO-ILE) (26%, n=25), SO-ILE (16.7%, n=16) and fish oil-based ILE (FO-ILE) (1%, n=1)
  - Nine patients (9.8%) reported a hypersensitivity reaction after exposure to the new oil source
    - Seven of these patients (77.8%) previously received SO-ILE, whereas two patients (22.2%) were naïve to all ILE types
    - Six of these patients (66.7%) received OO,SO-ILE and three patients (33.3%) received SO, MCT, OO, FO-ILE
    - Most hypersensitivity reactions were reported within the first hour of infusion (55.6%, n=5), with an onset of reaction ranging from seven minutes to 13 days
    - The most prevalent type of reaction was cutaneous (urticarial rash, swelling, erythema, hives, pruritis) (55.6%, n=5), followed by cutaneous reactions and throat itching (22.2%, n=2), and stomach pain or dry lips (22.2%, n=2)
    - Three patients (33.3%) required diphenhydramine, one required epinephrine (11.1%), and five (55.6%) did not require medication

Conclusions

Hypersensitivity reactions are rare in HPN patients with no known lifetime use of the oil source within the newly prescribed ILE products

- Causation cannot be determined from this project, as the hypersensitivity reaction could have been due to unrelated changes in the HPN formula, medication regimen or clinical status.
- Data provides insight into challenges home care clinicians may face with introducing a new oil source/ILE product in the HPN patient.

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Table 1. Sample characteristics and prevalence of hypersensitivity reaction after initiation or change to the ILE product (N=96)

	n (%)
Sex	
Female	57 (59.4)
Male	39 (40.6)
Reported food allergies[1]	
No	87 (90.6)
Yes	9 (9.4)
New ILE type introduced[2]	
OO (olive oil), SO (soybean oil) -ILE	54 (56.3)
SO, MCT (medium chain triglycerides), OO, FO (fish oil) -ILE	25 (26.0)
SO-ILE	16 (16.7)
FO-ILE	1 (1.0)
Direction of ILE dose	
No change	64 (66.7)
Initiation[3]	25 (26.0)
Increase	2 (2.1)
Decrease	5 (5.2)
Hypersensitivity reaction after ILE initiation/change	
No	85 (88.5)
Yes	9 (9.4)

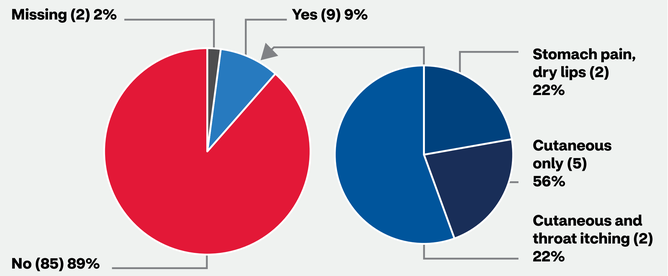
[1] Shellfish, peanut, soy, peaches, squash, strawberries, gluten, dairy, bee pollen (oral) (2 patients reported multiple allergies)
[2] Patients received SO-ILE before changing to another ILE type
[3] Patients documented as naive to all ILE types

Table 2. Description of patients with hypersensitivity reaction after initiation or change to ILE product (n=9)

	n (%)
Food allergies reported[1]	
No	7 (77.8)
Yes	2 (22.2)
Medication administered	
Diphenhydramine	3 (33.3)
Epinephrine	1 (11.1)
None/other	5 (55.6)
Onset to reaction	
Immediate (within first hour of infusion)	5 (55.6)
Delayed (within days)	3 (33.3)
Not reported	1 (0.1)
New ILE type introduced[2]	
OO (olive oil), SO (soybean oil) -ILE	6 (66.7)
SO, MCT (medium chain triglycerides), OO, FO (fish oil) -ILE	3 (33.3)
Change dose (gm/week)	
No change	6 (66.7)
Initiation[3]	2 (22.2)
Decrease	1 (11.1)

[1] One patient reported shellfish allergy; one patient reported peach and squash allergies (both changed from SO-ILE to OO,SO-ILE and experienced cutaneous reactions)
[2] Patients received SO-ILE before changing to another ILE type
[3] Patients documented as naive to all ILE types

Figure 1. Hypersensitivity reaction after ILE initiation/change



Cutaneous reactions include urticarial rash, swelling, erythema, hives and/or pruritus