Use of a Lipid Screening Tool to Identify Patients at Greater Risk of Infusion Reactions to Lipids in the Home Setting

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Background

Parenteral nutrition (PN) containing lipids has potential for causing hypersensitivity related reactions due to the components that make up the intravenous lipid emulsions (ILE).[1] There are 5 different types of lipids approved in the US for use in PN: Intralipid®[2] and Nutrilipid®[3], SMOF®[4], Clinolipid®[5], and Omegaven®[6]. As reported in the literature, rates of infusion reactions increase in patients with higher risk of hypersensitivity to fish, egg, soybean or peanut protein.[1,7]

At present, there is limited clinical guidance specific to the home setting for monitoring and administration of lipids with first dose. Due to this, home infusion organizations have traditionally imposed strict protocols, including required nursing observation time, when administering new ILE formulations. A lipid risk screening tool was previously implemented by this organization to ascertain patients at minimal risk for reaction and allow greater flexibility in patient care surrounding first doses of lipids. Secondary benefits of the lipid risk screening tool include optimizing the limited nursing time available and decreasing costs and waste associated with unused anaphylaxis kits.

The lipid risk screening tool assesses the potential level of risk the patient may experience based on previous use of ILE products; history of reaction to components such as eggs, soybean products, peanuts, and fish; history of anaphylaxis reactions to ILE or components; history of mild to moderate reactions or no history of reactions to ingredients or potential ingredients. Although there is high potential for hypersensitivity, the reporting shows low incidence of hypersensitivity reactions.

Purpose

The primary objective of this study was to compare the resources utilized in using a lipid risk screening tool versus not utilizing a lipid risk screening tool (which was the previous process). Specifically, this study assessed nursing time and drug costs related to the dispensing of anaphylaxis kits. The secondary objective was to assess the tolerability of ILE first doses in the home. It is hypothesized that ILE first doses in the home will be well tolerated after clinical review of patients using the lipid risk screening tool.

Methods

This was a multi-center, retrospective chart review analysis. Data was collected from the patients' electronic medical records and internal surveillance software. Inclusion criteria were patients with whom the lipid risk screening tool was utilized over a period of 12 months. Exclusion criteria for this study were patients less than 18 years of age, and ILE conversion that does not meet risk stratification (i.e., soy-based product conversion to soy-based product).

The selection process is detailed in *Figure 1*, and baseline characteristics are shown in *Table 1*. A cost analysis was completed to assess nursing time reduced, and medication dispenses avoided as a result of utilizing the lipid risk screening tool, as compared to the previous process. The patient charts were reviewed for infusion reactions of ILE first dose administration.

Figure 1: Selection Process

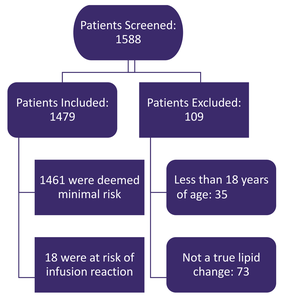


Table 1: Baseline Characteristics (n= 1479)

Baseline Characteristic	No Current Lipid (n=227, 15.3%)	Clinolipid® (n= 146, 9.9%)	Intralipid® (n=1075, 72.7%)	Nutrilipid® (n= 31, 2.1%)
Age, mean (SD)	**55 (16.1)**	**55.9 (16)**	**55.9 (16.3)**	**54.4 (16.9)**
18-49 yrs. (n, %)	88 (38.8)	40 (27.4)	352 (32.7)	11 (35.5)
50-64 yrs. (n, %)	66 (29.1)	60 (41.1)	354 (32.9)	8 (25.8)
65+ yrs. (n, %)	73 (32.1)	46 (31.5)	369 (34.3)	12 (38.7)
Allergies, n (%)	**22 (9.7)**	**3 (2.1)**	**46 (4.3)**	**6 (19.4)**
Eggs	3 (13.6)	0	3 (6.5)	1 (16.7)
Peanuts	4 (18.2)	1 (33.3)	3 (6.5)	1 (16.7)
Fish	11 (50.1)	2 (66.6)	32 (69.6)	2 (33.3)
Soybean, Soy products	1 (4.5)	0	2 (4.3)	0
Combination of 2 or more	3 (13.6)	0	6 (13)	2 (33.3)
ILE Therapy Change, n (%)				
Clinolipid®	95 (41.9)	0	657 (61.1)	25 (80.6)
Nutrilipid®	52 (22.9)	0	0	0
Intralipid®	1 (0.4)	0	0	0
SMOF®	79 (34.8)	146 (100)	417 (38.8)	6 (19.4)
Omegaven®	0	0	1 (0.09)	0

Figure 2: Level of Risk

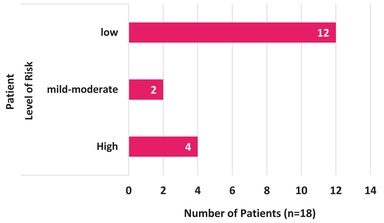
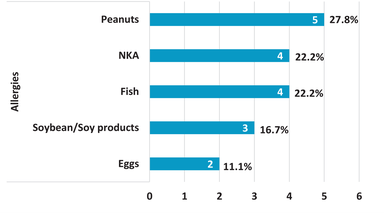


Figure 3: Allergies of At-Risk Population (N=18)



Results

During the 12-month period reviewed, there was a reduction in resources utilized as a result of the lipid risk assessment tool. Drug utilization related to anaphylaxis kit usage decreased, which resulted in a 99.3% drug cost reduction. There was also a 98.2% reduction in nursing time with the use of the lipid risk screening tool vs. the previous method. For the secondary objective of ILE first dose tolerability, the percentage of patients determined to be at any level of risk for ILE infusion reactions was 1.8%. The at-risk population was determined to have 66.7% of patients at low risk, 11.1% at mild-moderate risk and 22.2% at high risk *(see figure 2)*. There were 0 hypersensitivity reactions reported with the at-risk population. The types of allergies for the at-risk population are shown in *Figure 3*.

Discussion

Hypersensitivity to the components of parenteral nutrition (PN) is a rare but important complication of PN. Resources used in connection with hypersensitivity reaction were expected to be lower when utilizing the lipid assessment tool prior to first doses of ILEs in the home. A limitation of the study was voluntary reporting and manual documentation of adverse events.

Conclusion

This study demonstrated the utility of the lipid risk screening tool in appropriately assessing level of risk and potential need for additional resources. The lipid risk screening tool significantly reduced cost as well as time required by nurses to monitor patients for potential reactions. This study shows there is an opportunity to develop further training and education and insight for optimal usage of the lipid risk screening tool.

References

1. Christian VJ, Tallar M, Walia CLS, Sieracki R, Goday PS. Systematic Review of Hypersensitivity to Parenteral Nutrition. JPEN J Parenter Enteral Nutr. 2018;42(8): 1222-1229.
2. Intralipid [package insert]. Fresenius Kabi; 2023.
3. Nutrilipid [package insert]. B. Braun; 2023.
4. Smoflipid [package insert]. Fresenius Kabi; 2023.
5. Clinolipid [package insert]. Baxter; 2023
6. Omegaven [package insert]. Fresenius Kabi; 2023.
7. Mirtallo JM, Ayers P, Boullata J, et al. ASPEN Lipid Injectable Emulsion Safety Recommendations, Part 1: Background and Adult Considerations [published correction appears in Nutr Clin Pract. 2022 Apr;37(2):482]. Nutr Clin Pract. 2020;35(5):769-782. doi:10.1002/ncp.10496.

Disclosures

Authors of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation: Yoselin Flores; Jessica Monczka; Maria Giannakos; Annemarie Hocking; Suzanne Kluge: Nothing to disclose.

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