SMOFlipid® Case Study:
Home Parenteral Nutrition (HPN) Patient

Patient

65-year-old male who is underweight (BMI 16), and previously failed on oral diets and enteral feeding.

Medical/Surgical History

- J-pouch/colectomy reconstruction
- High output ostomy for 3 months, then underwent reanastomosis
- Continued diarrhea with increase in oral diet/fluids

Nutrition History

- Ht: 172 cm, Wt: 57 kg (weight increased from 47 kg to 57 kg)
- Home Parenteral Nutrition (HPN) Maintenance: 328 g/d dextrose, 60 g/d soybean oil-based lipid, 2000 cc/d fluid, 95 g/d protein, 7 days per week
- P.O. diet as tolerated
- Reduced soybean oil-based lipid infusion to 3 times per week after 6 weeks of therapy due to a significant increase in gamma-glutamyl transferase (GGT). Other liver function tests (LFTs) were stable and within normal limits

Rationale for SMOFlipid and Updated Nutrition Management

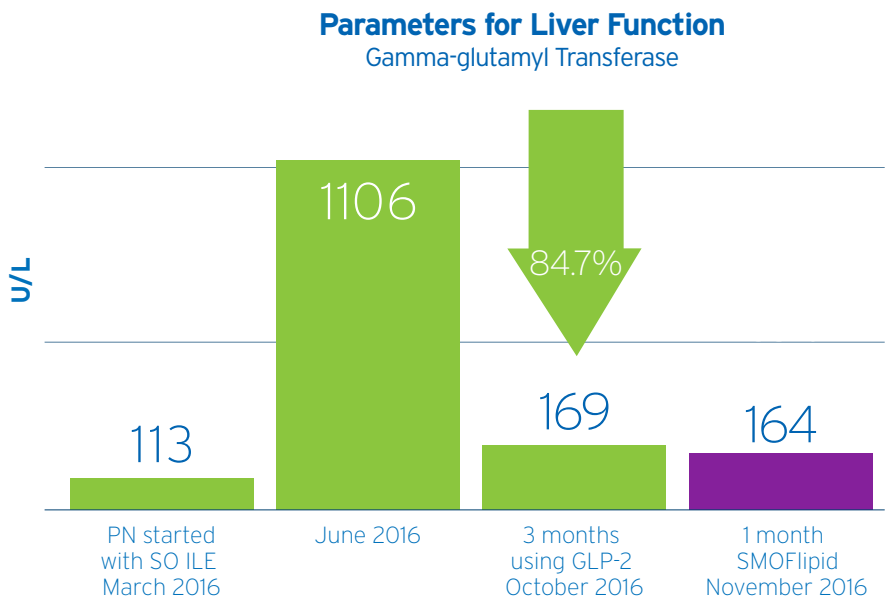
- 7 months after starting HPN, and reducing the amount of lipid per week, as well as initiating glucagon-like peptide-2 (GLP-2), the GGT was trending down, but remained consistently elevated
- Changed soybean oil-based lipid to SMOFlipid, 60 g (1.05 g/kg/d), continued 3 days per week and HPN 5 days per week
- After 1 month of starting SMOFlipid, GGT remained stable. Patient tolerated more foods orally, so decreased HPN to 4 days per week, dextrose rate was reduced, and SMOFlipid was added to every bag
- Over time, the patient's oral intake continued to improve and body weight remained stable

SMOFlipid®
Lipid Injectable Emulsion, USP 20%

See full Prescribing Information for SMOFlipid available at **www.FreseniusKabiNutrition.com/SMOFlipidPI.**

Please see Indications and Important Safety Information on next page.

CLINICAL RESULTS



Overall Clinical Assessment

During 1 month of treatment, the patient's GGT levels and weight remained stable. Other liver function tests remained stable and within normal limits. The addition of calories from SMOFlipid provided as part of each PN dose, given four times per week, contributed to the ability to reduce the dextrose infusion rate.

SMOFlipid® (lipid injectable emulsion, USP), for intravenous use
IMPORTANT SAFETY INFORMATION

What is SMOFlipid?

- Indicated in adult and pediatric patients as a source of calories and essential fatty acids for parenteral nutrition (PN) when oral or enteral nutrition is not possible, insufficient, or contraindicated.
- The hourly infusion rate in pediatrics should not exceed 0.75 mL/kg/hour and 0.5 mL/kg/hour in adults.

SMOFlipid should not be received by patients who have:

- A known allergy to fish, egg, soybean, or peanut, or to any of the active or inactive ingredients in SMOFlipid.
- Abnormally high levels of lipid (triglycerides) in the blood.

SMOFlipid may cause serious side effects including:

- **Serious Adverse Reactions with Rapid Infusion of Intravenous Lipid Emulsion in Neonates and Infants:** Strictly follow the recommended total daily dosage and do not exceed the maximum infusion rate. If poor clearance of fats occurs, the infusion should be stopped, and a medical evaluation started.
- **Risk of Parenteral Nutrition-Associated Liver Disease:** Parenteral nutrition-associated liver disease (PNALD) may progress to liver inflammation and damage caused by a buildup of fat in the liver with scarring and cirrhosis.
- **Allergic Reactions:** Contact your healthcare provider immediately if you are experiencing an allergic reaction.
- **Fat Overload Syndrome, Refeeding Syndrome, Elevated Triglycerides (Hypertriglyceridemia):** Your healthcare provider will monitor you for signs and symptoms of early infection and blood levels.

Monitoring/Laboratory Tests: The content of vitamin K may interfere with blood clotting activity of medications.

The most common side effects (>1%) in adult patients include nausea, vomiting, and high levels of glucose in the blood and **in pediatric patients include** low levels of red blood cells, vomiting, increased levels of liver enzymes (i.e., gamma-glutamyltransferase) and hospital-acquired infections.

These are not all the possible side effects associated with SMOFlipid. Call your healthcare provider for medical advice regarding SMOFlipid side effects. You are encouraged to report negative side effects of SMOFlipid. Contact Fresenius Kabi USA, LLC at: 1-800-551-7176 or FDA at: 1-800-FDA-1088 or www.fda.gov/medwatch. The FDA-approved product labeling can be found at https://freseniuskabinutrition.com/SMOFlipidPI.

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