SMOFlipid® Case Study:
Small Bowel Obstruction (SBO)

Patient

69-year-old overweight (29.9 kg/m^2 BMI) male with SBO and acute abdomen, who is unable to consume adequate calories or fluids orally for 3 days prior to admission; predisposed to hyperglycemia.

Medical/Surgical History

- Hypertension
- Gastroesophageal reflux disease
- Tubulovillous adenoma of the duodenum s/p pancreaticoduodenectomy
- SBO s/p exploratory laparotomy with repair and subsequent re-exploration due to wound dehiscence
- Post-operative ventral hernia

Operative Course

- Hospital Day 1 - s/p exploratory laparotomy with resection of 12 inches of ischemic jejunum due to SBO from incarcerated ventral hernia. Unable to close the abdomen
- Surgical intensive care unit (ICU) on a ventilator and nasogastric (NG) decompression with planned abdominal closure in 48-72 hours
- Hospital Day 4 - Abdominal wall closure with retention sutures and wound vacuum placement. The NG remained in place due to prior SBO and postoperative ileus

Nutrition Plan

- SMOFlipid initiated as part of parenteral nutrition (PN) regimen on hospital day 2
- Original PN Rx based on 75 kg ideal body weight (IBW):
  - Dextrose: 190 g (1.8 mg/kg/min)
  - Lipids: 75 g (1.0 g/kg/d)
  - Amino acids: 150 g (2 g/kg/d)
  - Total kcal: 1814 (24 kcal/kg/d)
- Revised PN Rx 2 days after PN initiation due to hyperglycemia:
  - Dextrose: 140 g/day (1.3 mg/kg/min)
  - Lipids: 100 g/day (1.3 g/kg/d)
  - Amino acids: 150 g/day (2 g/kg/d)
  - Total kcal: 2076 (28 kcal/kg/d)

SMOFlipid®
Lipid Injectable Emulsion, USP 20%

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

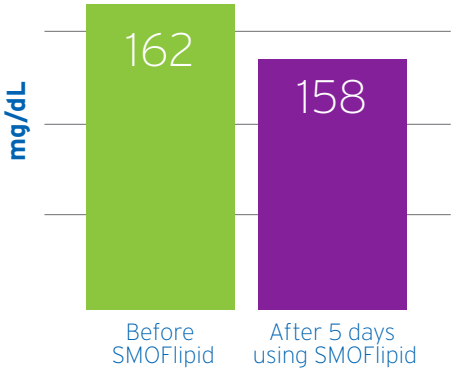
Please see Indications and Important Safety Information on next page.

Rationale for SMOFlipid and Updated Nutrition Management

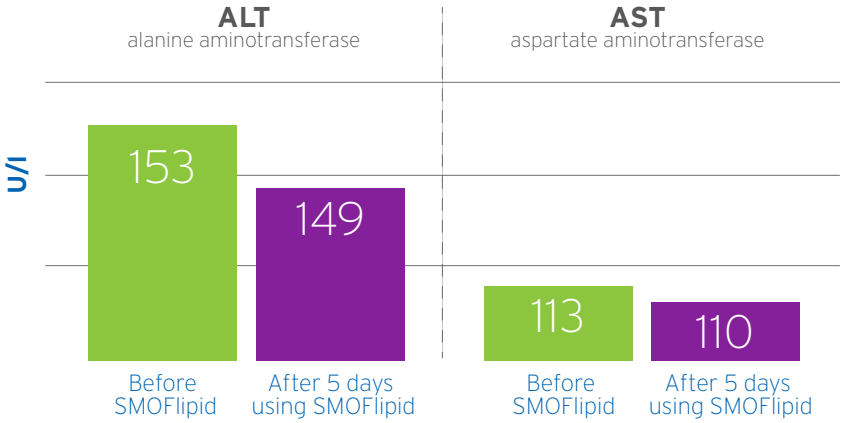
SMOFlipid was chosen as an early calorie source in the ICU. The dextrose content of his PN could be reduced with increased dosing of SMOFlipid. The early initiation of SMOFlipid provided adequate nutrition in a timely manner vs. restricting calories from fat if soybean oil (SO) lipid injectable emulsion (ILE) was the only option.

CLINICAL RESULTS

Triglyceride Change



Parameters of Liver Function



Overall Clinical Assessment

The patient received PN with SMOFlipid provided at 28 kcal/kg IBW/day with 2 g protein/kg IBW/day and showed no changes in triglycerides or liver function tests. Adequate protein helped to facilitate abdominal wound healing in the setting of glycemic management with added insulin to maintain serum glucose levels <180 mg/dL. Transition off PN on postoperative day (POD) 12 with regular diet tolerance and discharged home on POD 13.

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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