UCSF Benioff Children's Hospital Oakland

Smoflipid Protocol - NICU

PURPOSE: To outline indications for use, administration and monitoring of Smoflipids or "SMOF" for patients in the NICU on parenteral nutrition

LEVEL: Interdependent (MD, NNP, RD, PHA, RN)

SUPPORTIVE DATA: SMOF is an alternative lipid emulsion consisting of a combination of 4 types of lipid including soybean oil (30%), medium-chain triglycerides (30%), fish oil (15%) and olive oil (25 %).[1] This blend of lipids creates a balance of essential fatty acids including omega-3, 6 and 9 with shorter chain triglycerides to provide an energy dense source of nutrition with a greater anti-inflammatory profile than previously available. The ratio of omega 3 to omega 6 is notably identical to human breast milk.[2] The vitamin E level is increased to add provide greater antioxidant potential to protect long chain fats from peroxidation.[1, 2] Finally, the level of phytosterols is reduced by 60% in SMOF when compared to Intralipid. [2] Phytosterols are plant derived steroid compounds with potential toxicity to the neonatal liver. [2]

Prolonged (>1 month) parenteral nutrition with use of intravenous lipid emulsions increases risk for developing parenteral nutrition associated cholestasis (PNAC) or intestinal failure associated liver disease (IFALD).[2,3] The etiology is multi-factorial including interruption of bile flow and bilirubin excretion during fasting, stress from surgery, risk for bacterial overgrowth and translocation causing sepsis, immature neonatal hepatobiliary function, accumulation of phospholipids, excess phytosterols and predominance of omega 6 fatty acids promoting a proinflammatory state and an antioxidant imbalance associated with inadequate vitamin E.[2,3]

SMOF has been approved by the FDA for the use in adults and is currently being used off-label across the United States in the pediatric setting. Although limited research is presently available for use in the neonatal and pediatric populations, accumulating evidence suggests that SMOF is safe and adequate to meet nutritional requirements for patients with cholestasis. [2] Infants who are at high risk for cholestasis (prolonged dependence on parenteral nutrition, previous abdominal surgery and lack of enteral nutrition) may be good candidates for the use of SMOF.

Criteria to consider SMOF:

- Conjugated/Direct Bilirubin ≥1 mg/dL

Exclusionary criteria:

- Known hypersensitivity to fish, egg, soybean, or peanut protein, or to any of the active ingredients or excipients[1]

DOSAGE:

Intravenous Administration: Ordering: SMOF is ordered through EPIC when ordering parenteral nutrition. Order lipids by mL/day using the usual TPN + lipids order set. .

Maximum dosing on 100% PN should be 3 g/kg/day and minimum dosing on complete or mostly PN should be 2 g/kg/day to prevent essential fatty acid deficiency.[4]

- Initiate at 1 g/kg/day and check triglycerides
- Advance by 1 g/kg/day if TG within normal limits
- Once at goal, recheck TG once weekly

A lower dose may be sufficient, e.g. 1 g/kg/day, for patients receiving significant enteral nutrition, perhaps half of their enteral goal.

Administration: SMOF is administered the same as Intralipid

ASSESSMENT: Weekly monitoring - neonatal chemistry panel, conjugated bilirubin, triglycerides

1. Consider decreasing by 50% x 48 hours if triglycerides > 200 mg/dL.
    a. Recheck triglyceride level
    b. If rechecked level < 150 mg/dL, advance SMOF by 0.5 g/kg
2. SMOF provision less than 2 g/kg for 2+ weeks may result in essential fatty acid deficiency if the patient is solely on PN. The risk is less if the patient is on any volume of enteral feeds.
3. If a patient is on less than 2 g/kg SMOF >1 month while on full PN, consider obtaining Fatty Acid Profile, Essential (C12 – C22) (1 mL blood)
    a. If deficient, suggest increase dose by 1 g/kg/d to maximum 3 g/kg
    b. Recheck x 1 week
    c. Initiate enteral feeds as soon as medically appropriate

DOCUMENTATION: RD documents use in weekly progress notes in electronic medical record

REFERENCES:

1. Smoflipid Clinical guidelines regarding the use of alternative intravenous lipid emulsions (IVLEs). http://smoflipid.com/clinical-guidelines.html.
2. Al-Shahwani, N.H. & Sigalet, D.L. Pathophysiology, prevention, treatment, and outcomes of intestinal failure-associated liver disease. Pediatr Surg Int (2017) 33: 405 - 411.
3. Diamond IR, Grant RC, Pencharz PB, de Silva N, Feldman BM, Fitzgerald P, Sigalet D, Dicken B, Turner J, Marchand V, Ling SC, Moore AM, Avitzur Y, Wales PW. Preventing the progression of intestinal failure-associated liver disease in infants using a composite lipid emulsion: a pilot randomized controlled trial of SMOFlipid. JPEN J Parenter Enteral Nutr. 2016 Feb. ‘
4. Mehta NM, Compher C and Directors. A.S.P.E.N. Clinical guidelines: Nutrition support of the critically ill child. JPEN J Parenter Enteral Nutr 2009; 33:260-76.

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