Trust Guideline for the Management of: Clinical Guideline for Use of SMOFlipid in Neonatal and Paediatric Patients at Risk of Intestinal Failure Associated Liver Disease

A clinical guideline

| For Use in: | Jenny Lind Children’s Hospital |
| By: | Registered Paediatric Nurses, Medical Staff, Paediatric Dietitians and Paediatric Pharmacists |
| For: | Infants, children and adolescents with or at risk of developing, intestinal failure associated liver disease (IFALD). |
| Division responsible for document: | Womens and Childrens |
| Key words: | Intestinal failure associated liver disease, SMOFlipid®, Parenteral Nutrition |
| Name and job title of document author’s: | Dr Mary-Anne Morris, Consultant, Member of EoEPGN Dr G Briars, Consultant, member of EoEPGN (adapted from EoEPGN Guidelines) |
| Name and job title of document author’s Line Manager: | Frances Bolger, Chief of Division |
| Supported by: | Paediatric Nutrition Support Team |
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This guideline has been approved by the Trust's Clinical Guidelines Assessment Panel as an aid to the diagnosis and management of relevant patients and clinical circumstances. Not every patient or situation fits neatly into a standard guideline scenario and the guideline must be interpreted and applied in practice in the light of prevailing clinical circumstances, the diagnostic and treatment options available and the professional judgement, knowledge and expertise of relevant clinicians. It is advised that the rationale for any departure from relevant guidance should be documented in the patient's case notes. The Trust's guidelines are made publicly available as part of the collective endeavour to continuously improve the quality of healthcare through sharing medical experience and knowledge. The Trust accepts no responsibility for any misunderstanding or misapplication of this document.
1. Objectives

To provide a consistent management to infants, children and adolescents with or at risk of developing, intestinal failure-associated liver disease (IFALD) across the East of England Paediatric Gastroenterology Network.

2. Introduction

The first line lipid component of parenteral nutrition (PN) for paediatric use is currently 20% Intralipid®. Its use is required primarily in preterm neonates and in patients with intestinal failure (IF) which is defined as gastrointestinal problems resulting in dependence on PN for some or all nutrition for 27 or more days, consecutively or in total. One of the most significant complications of long term PN is intestinal failure-associated liver disease (IFALD) which occurs in up to 50% of children after 6-12 weeks on PN (1). Possible mechanisms include lack of enteral feeding, reduced gut hormones secretions, reduction of bile flow and biliary stasis leading to the development of cholestasis, biliary sludge and gallstones, which exacerbate hepatic dysfunction (2). Premature infants, infants born small for dates, those with congenital gut anomalies and severe acquired conditions resulting in short gut syndrome or in gut dysmotility are most at risk.

The pro-inflammatory properties of soya based lipids (e.g. Intralipid®) are widely considered to have a causative role in inducing IFALD. There is now increasing evidence that change to a lipid preparation containing fish oils can reverse liver disease over a 4-6 week period (3,4,5,6,7,10). One such preparation comprises soya, medium chain triglycerides, olive oil and fish oil (SMOFlipid®).

Two randomised controlled trials have shown SMOF to decrease plasma bilirubin and gamma-glutamyl transpeptidase (GGT) levels in comparison to the levels seen with traditional soybean lipids. SMOFlipid® has also been shown to increase omega 3 fatty acids and alpha tocopherol without changing lipid peroxidation. This is thought to protect premature infants from increased levels of oxidative stress and may benefit their cognitive development and visual capacity.(8)
The use of a multi-lipid emulsion is advised as one of the preventative and/or treatment strategies but further studies are required to establish whether SMOFlipid® can reverse PN-associated liver disease.

SMOFlipid® is now used by intestinal failure units such as Great Ormond Street Hospital and Birmingham Children’s Hospital. A survey of further 32 paediatric centres shows SMOFlipid® to be the preferred lipid for patients who develop signs of liver dysfunction on Intralipid® (9). The British Society of Paediatric Gastroenterology, Hepatology and Nutrition (BSPGHAN) recommend the consideration of SMOFlipid® in children with IFALD.

Some units (e.g. Addenbrookes, Newcastle, and Nottingham - personal communications) are now using SMOFlipid® as a first line lipid in high risk infants.

3. Safety and efficacy

A randomised controlled trial comparing SMOFlipid® and traditional soybean oil based emulsion in premature babies has shown no difference in adverse events, serum triglyceride, vital signs, local tolerance between study and control groups. It showed a potential beneficial influence on cholestasis, -3 fatty acid, and vitamin E status in the SMOFlipid® group.

4. Indication

The East of England Paediatric Gastroenterology Network (EEPGN) recommends that SMOFlipid® is considered for the following paediatric patients:

1. PN-dependant for over 27 days (even if LFTs normal)
2. Patients at high risk of needing PN for >27 days
3. Significant liver dysfunction before 27 days on PN (conjugated bilirubin >50 mmol/l or ultrasound evidence of splenomegaly)
4. Patients transferred into units who are established on SMOFlipid® already

- Paediatric patients meeting the criteria for use of SMOFlipid® should be discussed with a consultant in paediatric gastroenterology or consultant neonatologist.
- Typically SMOFlipid® use will be for the duration of inpatient PN

5. Clinical audit standards

1. SMOFlipid® considered for patients reaching criteria (100%)
2. Patients considered for use of SMOFlipid® discussed with consultant paediatric gastroenterologist, consultant with interest in paediatric gastroenterology or consultant neonatologist (100%)

6. Summary of development and consultation process undertaken before registration and dissemination

This guideline has been developed by the East of England Paediatric Gastroenterology Network. This document has been updated after literature search of recent SMOFlipid®-related studies. During its development it has been circulated for comment to: Paediatric Nutritional group in Norfolk and Norwich University Hospital. This was reviewed in August.
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2018 and the requirement to log patients onto National database deleted as this is no longer active. In 2018 literature review revealed only reference 10 to be added.

7. Distribution list/ dissemination method

Trust Intranet.

8. References/ source documents


7. Rayyan et al. Effect of a new type of lipid emulsion based on soybean oil, MCT, olive oil and fish oil (SMOF 20%) in preterm infants. Pediatr Crit Care Med. 2007; 8: (Suppl) ;S318


10. MI Attard. Change from intralipid to SMOF lipid is associated with improved liver function in infants with PN associated liver disease

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