

SAFETY AND EFFICACY OF FISH OIL-BASED LIPID EMULSION IN THE TREATMENT OF INTESTINAL FAILURE ASSOCIATED LIVER DISEASE: 11 YEAR EXPERIENCE IN A TERTIARY NEONATAL INTENSIVE CARE UNIT

Anne L Smazal¹, Athis Arunachalam², Joseph Hagan², Laura Gollins², Amy Hair², Muralidhar Premkumar²

¹ Baylor College of Medicine, Department of Pediatrics, Neonatology

² Baylor College of Medicine, Pediatrics, Neonatology

Background: Fish oil-based lipid emulsion (FOLE; Omegaven®) has been used to treat Intestinal Failure-Associated Liver Disease (IFALD), a complication associated with the use of Soybean oil-based lipid emulsion (SOLE; Intralipid®). At Texas Children's Hospital, Houston, FOLE was provided through a compassionate use protocol for the treatment of IFALD from 2007 until its FDA approval in 2018. This report presents the comprehensive results of this 11 year protocol.

Materials/Methods: Infants enrolled in this protocol to receive FOLE in the treatment of IFALD at Texas Children's Hospital, Houston Texas from 2007 to 2018 were included. Eligibility criteria: age > 14 days, conjugated bilirubin (CB) ≥ 2 mg/dL, and expected parenteral nutrition need of >28 days. For the analysis of blood stream infections (BSI): Infants with incomplete records of lipid use were excluded, bivariate analysis was used to compare BSI incidence per patient day and line day, and a multivariable Poisson regression model was fit to adjust for several independent predictor variables.

Results: 278 infants (M: F: 183:95) with a mean GA of 29.7±5 weeks received FOLE. The mean CB level at start of FOLE was 5.3±3.9 mg/dL (Range 2-26 mg/dL). Resolution of cholestasis was noted in 232 (83.4%) infants within a mean duration of 43 ± 29 days. 43 (15.4%) infants died. 3 infants required orthotopic liver transplants (OLT), none since 2010. For the analysis of BSI, 153 patients were analyzed. A total of 146 BSIs occurred in 93 patients. BSI rate was higher during SOLE treatment as compared to FOLE treatment (12.6 vs 6.1 per 1000 patient days, p<0.001), but not different when lipid dose was 1g/kg/d in both groups (9 vs 6.1 per 1000 patient day, p = 0.1). Lower GA, SOLE treatment, and higher lipid dose were associated with higher BSI rate (p=0.021, <0.001, and <0.001, respectively).

Conclusions: Compassionate use therapy with FOLE facilitated resolution of cholestasis in majority of infants with IFALD thus resulting in an improvement in survival and a decreased need for OLT. Use of FOLE was also associated with lower rate of BSI when compared to SOLE in infants with IFALD. The results of this large study further support the safety and efficacy of FOLE in the treatment of infants with IFALD.