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COMPARISION OF SMOF BASED AND SOY (INTRA LIPID) BASED PARENTERAL NUTRITION AMONG PRETERM INFANTS -A RETROSPECTIVE AND PROSPECTIVE STUDY

Neonatology

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ABSTRACT

Introduction: Preterm infants, particularly those with very low birth weight (VLBW <1500 g), often face nutritional challenges due to gastrointestinal immaturity and increased metabolic demands. Parenteral nutrition (PN) plays a critical role in meeting their early nutritional needs, with lipid emulsions serving as vital energy sources and providing essential fatty acids. Conventional soybean oil-based emulsions (Intralipid) have been associated with pro-inflammatory effects and parenteral nutrition-associated liver disease (PNALD). SMOF, a multi-component lipid emulsion composed of soybean oil, medium-chain triglycerides, olive oil, and fish oil, has been introduced to overcome these limitations. **Aim and Objective:** To compare SMOF-based and soybean oil-based lipid emulsions regarding growth parameters, risk of metabolic bone disease (MBD), sepsis, retinopathy of prematurity (ROP), bronchopulmonary dysplasia (BPD), necrotizing enterocolitis (NEC), and overall outcomes in preterm neonates. **Materials and Methods:** This combined retrospective and prospective observational cohort study was conducted at the NICU of Rajarajeswari Medical College and Hospital, Bangalore. Preterm neonates (<37 weeks, <2.5 kg) requiring PN >5 days were enrolled between April 2023 and September 2024. Demographic, clinical, biochemical, and outcome data were collected. Ethical clearance and parental consent were obtained. **Results:** SMOF recipients showed significantly better birth weight (p = 0.003), earlier attainment of full feeds (p = 0.021), improved weight gain (p = 0.001), and earlier initiation of breastfeeding (p = 0.019). Serum phosphorus levels were significantly higher (p = 0.005) in SMOF, suggesting reduced MBD risk. Rates of sepsis, NEC, BPD, and ROP were comparable across groups. **Conclusion:** SMOF lipid emulsions demonstrated superior clinical benefits over Intralipid, enhancing nutritional outcomes without increasing complications, thus representing a preferable PN option in preterm infants.

KEYWORDS

SMOF; Intralipid; Preterm Infants; Parenteral Nutrition; Metabolic Bone Disease.

INTRODUCTION

Preterm birth, defined as delivery before 37 completed weeks of gestation, remains one of the leading causes of neonatal morbidity and mortality worldwide. Globally, approximately 15 million infants are born prematurely each year, and many of them present with very low birth weight (VLBW, <1500 g) or extremely low birth weight (ELBW, <1000 g). These neonates have unique nutritional challenges due to their immature gastrointestinal (GI) system, limited glycogen and fat stores, and increased metabolic demands for rapid organ development and growth. While enteral feeding is the preferred mode of providing nutrients, a significant proportion of preterm infants cannot tolerate adequate enteral feeds during the early postnatal period because of gastrointestinal immaturity, feeding intolerance, or heightened risk of complications such as necrotizing enterocolitis (NEC). For these reasons, parenteral nutrition (PN) plays a crucial role in meeting their immediate nutritional needs, ensuring appropriate weight gain, neurodevelopment, and survival during the critical early weeks of life (1-3).

PN provides carbohydrates, amino acids, vitamins, trace elements, electrolytes, and lipids, each serving distinct and essential roles. Among these, lipid emulsions are particularly vital because they provide a dense energy source, supply essential fatty acids (EFAs), and form key structural components of cell membranes. Lipids also serve as precursors of bioactive signaling molecules, including eicosanoids, which are vital for immune regulation and inflammatory control. Essential fatty acids, primarily linoleic acid (ω-6) and alpha-linolenic acid (ω-3), are indispensable for brain development, retinal maturation, and overall growth. Traditionally, soybean oil-based lipid emulsions (Intralipid) have been the standard choice in neonatal PN for several decades. However, concerns have been raised regarding their high content of ω-6 polyunsaturated fatty acids (PUFAs) and phytosterols, both of which have been implicated in inflammatory responses and parenteral nutrition-associated liver disease (PNALD). These adverse effects are particularly problematic in premature neonates who often require prolonged PN due to delayed tolerance of enteral feeds (4-6).

Soybean oil emulsions are composed mainly of long-chain triglycerides (LCTs) derived from soybean oil, which is rich in linoleic acid and other ω-6 PUFAs. While these fatty acids are essential, an imbalanced ω-6 to ω-3 ratio may predispose neonates to a pro-inflammatory state, increasing the risk of complications such as bronchopulmonary dysplasia (BPD) and sepsis. Additionally, soybean-based emulsions are high in phytosterols, which have been associated with impaired bile flow and cholestasis, leading to PNALD in infants on long-term PN. Another limitation of Intralipid is the lack of fish oil-derived ω-3 fatty acids, particularly docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA), which are critical for neuroprotection, modulation of inflammation, and normal visual development (5, 7).

To address these concerns, newer multi-source lipid emulsions have been formulated, among which SMOF (an emulsion containing soybean oil, medium-chain triglycerides [MCTs], olive oil, and fish oil) has become one of the most promising alternatives. SMOF is designed to provide a more balanced fatty acid composition, combining approximately 30% soybean oil, 30% MCTs, 25% olive oil, and 15% fish oil. Each component contributes unique benefits: soybean oil ensures an adequate supply of EFAs, MCTs provide rapidly metabolizable energy and are less dependent on lipase activity, olive oil (rich in monounsaturated fatty acids such as oleic acid) offers oxidative stability and anti-inflammatory properties, while fish oil delivers significant amounts of ω-3 fatty acids (DHA and EPA), which are well known for their neuroprotective and anti-inflammatory roles. This composition results in a lower ω-6 to ω-3 ratio, reduced phytosterol content, and higher levels of α-tocopherol (vitamin E), which acts as an antioxidant and protects against lipid peroxidation (8, 9).

One of the most significant potential benefits of SMOF lies in its impact on neurodevelopment. DHA, in particular, is an essential component of neuronal membranes and plays a critical role in synapse formation, myelination, and visual function. Since preterm infants have a limited capacity to synthesize DHA from its precursor alpha-linolenic acid, direct supplementation through PN is particularly valuable. Several studies have reported that infants receiving SMOF-based PN demonstrate higher plasma and red blood cell DHA levels compared to those receiving Intralipid, which may translate into improved visual and cognitive outcomes later in life. Additionally, the presence of ω-3 fatty acids contributes to the production of anti-inflammatory mediators, such as resolvins and protectins, which may lower the risk of inflammatory complications such as NEC, BPD, and retinopathy of prematurity (ROP) (10, 11).

SMOF shows clear advantages in liver health, as parenteral nutrition-associated liver disease (PNALD) remains a major concern in preterm infants on prolonged PN due to their immature hepatic function. The pathogenesis of PNALD involves oxidative stress, phytosterol toxicity, and an imbalance of pro- and anti-inflammatory lipid mediators. With its reduced phytosterol content and ω-3 fatty acid enrichment, SMOF demonstrates hepatoprotective effects, lowering conjugated bilirubin levels, improving liver enzymes, and reducing cholestasis compared to traditional soybean emulsions. Additionally, MCTs in SMOF offer rapidly metabolizable energy, while ω-3 fatty acids may decrease inflammation and sepsis risk. Though both SMOF and Intralipid meet energy and essential fatty acid needs, SMOF's composition may offer broader long-term benefits. Comparative studies remain essential to establish its efficacy, safety, and potential neurodevelopmental advantages, refining neonatal nutritional strategies (12-14).

To compare soybean oil, medium chain triglycerides, olive oil, and fish oilcontaining (SMOF) lipid emulsionand soy-based lipid emulsion on outcomes like sepsis, cholestasis, retinopathy of prematurity in a low-birth-weight preterm infants.

MATERIALS AND METHODS

This observational cohort study, conducted at the NICU of Rajarajeswari Medical College and Hospital, Bangalore, compared outcomes of preterm low birth weight neonates (<2.5 kg) receiving SMOF or soy-based (Intralipid) lipid emulsions as part of TPN. Data were collected retrospectively (April 2023–March 2024) and prospectively (April–September 2024). Eligible neonates had gestational age <37 weeks, weight <2500 g, and required PN >5 days. Those with major anomalies, genetic syndromes, liver disease, or incomplete records were excluded. Ethical approval (IEC/RRMCH/2023/PN-45) and informed parental consent were obtained, with confidentiality maintained according to institutional guidelines and the Declaration of Helsinki.

RESULTS

Table 1: Demographic Characteristics of the Study Study Neonates

Demographic characteristics	SMOF		Intralipid		p-value
	Mean	SD	Mean	SD	
Gestational Age (weeks)	30.70	2.32	29.34	1.74	0.131
Birth Weight (kg)	1.080	0.23	0.994	0.222	0.003
APGAR at 1 min	6.30	1.07	6.34	0.71	0.7439
APGAR at 5 min	8.00	0.88	8.00	0.43	0.3783
No of days in hospital	42.27	16.71	43.61	23.72	0.3874
Age of Lipid emulsion initiation (hrs)	19.68	4.89	25.68	4.11	1.689
Days in which TPN Given	8.60	3.23	6.43	2.86	0.087

The table compares the demographic characteristics of neonates receiving SMOF versus Intralipid emulsions. Both groups had similar gestational ages and APGAR scores, with no significant difference ($p > 0.05$). However, birth weight was significantly higher in the SMOF group ($p = 0.003$). Other variables, including hospital stay duration, lipid initiation age, and TPN days, showed no statistically significant differences, indicating comparable baseline characteristics except for birth weight.

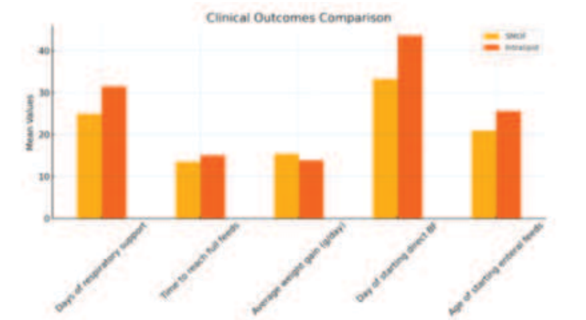

Figure 1: Clinical Characteristics of the Study Neonates

The figure compares clinical outcomes between SMOF and Intralipid groups. Neonates receiving SMOF required fewer days of respiratory support and reached full feeds slightly earlier than those on Intralipid. SMOF also showed marginally better average weight gain and earlier initiation of direct breastfeeding. Overall, SMOF appears to promote faster recovery and feeding readiness compared to Intralipid.

Table 2: Dose of Aminiven, SMOF and Intralipid Given to Neonates

Nutritional Doses	Mean	Standard Deviation	p-value
Dose of Aminiven (gm/kg/day)	2.02	0.12	0.201
Dose of SMOF Lipids (gm/kg/day)	1.04	0.20	0.123
Dose of Intralipid (gm/kg/day)	1.04	0.21	0.143

The table shows the mean doses of Aminiven, SMOF lipids, and Intralipid administered to neonates. Aminiven had the highest average dose (2.02 gm/kg/day), while SMOF and Intralipid were both given at 1.04 gm/kg/day with comparable standard deviations. None of the differences in doses were statistically significant ($p > 0.05$), indicating uniform nutritional administration across groups.

Table 3: Clinical Parameters to Determine Risk of Metabolic Bone Disease in Patients

Clinical parameters	SMOF		Intralipid		t-test	p-value
	Mean	SD	Mean	SD		
ALP	492.72	248.92	598.44	246.24	-1.64	0.105
Phosphorus	4.836	0.7605	4.1166	1.1970	2.89	0.005

The table compares ALP and phosphorus levels between SMOF and Intralipid groups to assess metabolic bone disease risk. ALP levels were higher in the Intralipid group, but the difference was not statistically significant ($p = 0.105$). Phosphorus levels were significantly higher in the SMOF group ($p = 0.005$), suggesting better bone mineralization potential with SMOF compared to Intralipid.

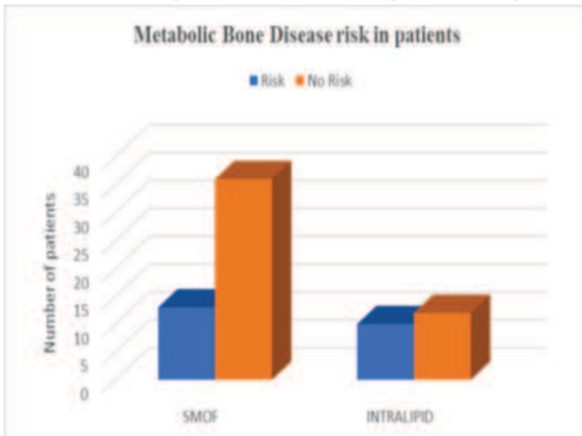

Figure 2: Risk of Metabolic Bone Disease in Patients

The chart compares the risk of metabolic bone disease between SMOF and Intralipid groups. A higher number of neonates receiving SMOF fell into the "no risk" category compared to those on Intralipid. In contrast, the Intralipid group had a relatively higher proportion of patients at risk. This suggests SMOF may offer better protection against metabolic bone disease.

Table 4: Outcomes in the Study Neonates

Parameters	SMOF		Intralipid		p-value
	Mean	SD	Mean	SD	
Days of respiratory support	24.91	18.02	31.43	15.76	0.683
Time taken to reach full feeds (days)	13.53	7.28	15.00	4.44	0.021
Average rate of weight gain (gms)	15.36	1.74	13.81	1.11	0.001
Days of starting direct breast feeding	33.26	15.45	43.65	11.26	0.019
Age of starting enteral Feeds (weeks)	20.89	4.91	25.56	4.25	1.078

The table compares neonatal outcomes between SMOF and Intralipid groups. SMOF significantly improved time to reach full feeds ($p = 0.021$), average weight gain ($p = 0.001$), and earlier initiation of direct breastfeeding ($p = 0.019$) compared to Intralipid. Although days of respiratory support and age of starting enteral feeds were slightly lower in SMOF, these differences were not statistically significant ($p > 0.05$).

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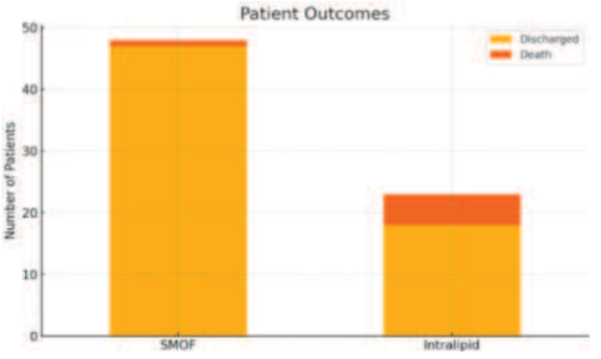

Figure 3: Outcomes After Given SMOF or Intralipid to Neonates

The chart illustrates patient outcomes following SMOF or Intralipid administration in neonates. A larger number of neonates in the SMOF group were successfully discharged compared to the Intralipid group, indicating better clinical recovery. Mortality was slightly lower in the SMOF group. These findings suggest SMOF may provide improved survival and discharge rates compared to Intralipid.

Table 5: Retinopathy of Prematurity in the Neonates

	SMOF (N)	N%	Intralipid (N)	N%	Total	Total %	p-value
ROP present							
Stage 1 ROP	15	21.127	6	8.45	21	29.58	0.883
Stage 2 ROP	10	14.085	6	8.45	16	22.54	0.326
ROP absent							
No ROP	13	18.310	7	9.85	20	28.17	0.614
Mild TAR	2	2.817	0	0	2	2.82	0.335
Moderate TAR	9	12.676	3	4.22	12	16.90	0.860
Total	49	69.0140845	22	30.98	71	100.00	
p-value							

The table compares the incidence and severity of retinopathy of prematurity (ROP) between SMOF and Intralipid groups. Stage 1 and Stage 2 ROP were more frequent in the SMOF group, but the differences were not statistically significant ($p > 0.05$). Similarly, the rates of no ROP, mild TAR, and moderate TAR were comparable between groups. Overall, neither lipid emulsion showed a significant impact on ROP risk or severity.

Table 6: Infection Among Neonates

	SMOF (N)	N%	Intralipid (N)	N%	Total	Total %	p-value
SEPSIS							1.0
Early	7.00	9.86	6.00	8.45	13.00	18.31	
Onset	11.00	15.49	11.00	15.49	22.00	30.99	
BACTEK BLOOD CULTURE							0.3549
CONS+	5.00	7.04	0.00	0.00	5.00	7.04	
KLEBSIELLA PNEUMONIA	3.00	4.23	2.00	2.82	5.00	7.04	
NO GROWTH	48.00	67.61	21.00	29.58	69.00	97.18	
STAPH-LOCOCCUS HEMO-LYTICUS	2.00	2.82	0.00	0.00	2.00	2.82	
BPD							0.223
Evolving	2.00	2.82	1.00	1.41	3.00	4.23	
Grade 1	0.00	0.00	1.00	1.41	1.00	1.41	
Grade 2	2.00	2.82	0.00	0.00	2.00	2.82	
NEC							0.2635
Suspected NEC	1.00	1.41	0.00	0.00	1.00	1.41	
Stage 2 NEC	2.00	2.82	2.00	2.82	4.00	5.63	

The table compares infection rates and complications between SMOF and Intralipid groups. Both groups showed similar rates of early and late-onset sepsis ($p = 1.0$), with no significant difference in blood culture results ($p = 0.3549$), where most samples showed no growth. Incidences of bronchopulmonary dysplasia (BPD) and necrotizing enterocolitis (NEC) were low and comparable between groups ($p > 0.05$). Overall, neither lipid emulsion significantly influenced infection risk or related complications.

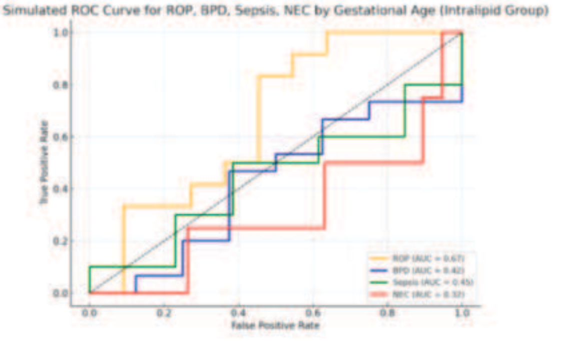

Figure 4: Relationship Between Gestational Age and Incidence of ROP, BPD, Sepsis and NEC in Patients Who Were Given SMOF

The ROC curve illustrates the predictive relationship between gestational age and the incidence of ROP, BPD, sepsis, and NEC in the Intralipid group. ROP shows the highest predictive accuracy with an AUC of 0.67, indicating a moderate association. BPD (AUC = 0.42), sepsis (AUC = 0.45), and NEC (AUC = 0.32) demonstrate weak predictive values. Overall, gestational age is a better predictor for ROP compared to other complications in this group.

DISCUSSION

Parenteral nutrition (PN) remains a cornerstone in the management of preterm neonates, especially those with very low birth weight who cannot tolerate full enteral feeding due to gastrointestinal immaturity (Greenberg et al., 2020). Lipid emulsions are critical in PN for providing essential fatty acids and energy for growth, immune function, and neurodevelopment. Conventional soy-based emulsions such as Intralipid, though widely used, have been associated with pro-inflammatory effects due to their high omega-6 polyunsaturated fatty acid (PUFA) content and risk of parenteral nutrition-associated liver disease (PNALD) (Kanemaru et al., 2014) (15, 16).

To overcome these limitations, multi-component lipid emulsions like SMOF—comprising soybean oil, medium-chain triglycerides, olive oil, and fish oil—have been introduced. SMOF provides a favorable omega-6 to omega-3 ratio, with anti-inflammatory and antioxidant properties derived from omega-3 fatty acids (fish oil) and mono-unsaturated fats (olive oil) (Klek et al., 2013). Several studies suggest SMOF improves liver function, reduces cholestasis, and may enhance clinical outcomes in preterm infants (Yang et al., 2016). In the Indian context, evidence remains limited, prompting this study to evaluate SMOF versus Intralipid in terms of growth parameters, liver enzyme trends, sepsis, PNALD, and NICU stay (Choudhary et al., 2018)(17-19).

Demographic analysis showed no significant difference in gestational age between SMOF and Intralipid groups (30.70 ± 2.32 vs. 29.34 ± 1.74 weeks, $p = 0.131$), though SMOF neonates had higher birth weights ($p = 0.003$). APGAR scores, hospital stay, timing of lipid initiation, and TPN duration were similar, corroborating Greenberg et al.'s matched-cohort findings of demographic equivalence (Greenberg et al., 2020). Clinical characteristics such as sex distribution and delivery mode were comparable, though extreme prematurity was higher in the Intralipid group ($p = 0.0083$). Similar observations were noted by Kanemaru et al. (15, 16).

Dosing of Aminiven, SMOF, and Intralipid was within standard ranges, with stable biochemical parameters across groups. Liver enzyme levels, particularly alkaline phosphatase, remained acceptable, echoing Klek et al.'s findings of reduced liver dysfunction with SMOF (17).

SMOF recipients achieved full enteral feeds earlier, exhibited better weight gain, and transitioned to breastfeeding sooner compared to Intralipid infants. While respiratory outcomes were similar, SMOF improved phosphorus levels and slightly reduced alkaline

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phosphatase, indicating a lower risk of metabolic bone disease (MBD). Yang et al. and Zhang et al. have similarly reported enhanced nutritional outcomes with SMOF. MBD incidence did not differ significantly between groups (p = 0.136), aligning with Choudhary et al. (18-20).

Retinopathy of prematurity (ROP) rates were also comparable between groups, despite trends in larger studies suggesting reduced severity with SMOF (Poy et al., 2024; Tu et al., 2020). Sepsis, bronchopulmonary dysplasia (BPD), and necrotizing enterocolitis (NEC) rates were not significantly different. Culture positivity occurred only in SMOF neonates, but without statistical significance. These results are consistent with multicenter studies by Yang et al. and Asfour et al., which reported no increased infectious risks with SMOF (18, 21-23).

CONCLUSION

SMOF-based lipid emulsions demonstrated superior clinical outcomes compared to conventional soybean-based Intralipid emulsions in preterm neonates. Infants receiving SMOF achieved faster feeding milestones, better weight gain, and improved serum phosphorus levels, indicating a reduced risk of metabolic bone disease. Importantly, SMOF use was associated with lower mortality rates without increasing the incidence of sepsis, NEC, BPD, or ROP. The unique multi-source composition of SMOF, which includes DHA-rich fish oil, medium-chain triglycerides, and hepatoprotective olive oil, contributes to its enhanced safety and efficacy. These findings support SMOF as a preferred parenteral nutrition option for vulnerable preterm neonates.

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