A description of liver function tests amongst adult patients in the British Columbia Home Parenteral Nutrition (BC HPN) Program who have changed from a soybean oil emulsion to a mixed-lipid emulsion

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INTRODUCTION

Intravenous lipid emulsions (ILEs) refer to the fat component of parenteral nutrition (PN), a form of nutritional therapy for patients who cannot feed entirely via the gastrointestinal tract. However, long-term ILE use may be associated with PN-associated liver disease (PNALD)¹. Soybean oil (SO)-based ILE, e.g. Intralipid® may contribute to disease development¹. Consequently, SMOFlipid®, a mixed oil-based ILE has been developed¹⁻³. Current literature suggests a role for SMOFlipid® in preventing, treating, or managing PNALD in acute-care and surgical settings⁴⁻⁶. However, a gap in knowledge still exists regarding its use for adult patients on home PN, where ILEs are used long-term.

Purpose: To describe the liver function tests of adult patients in the BC HPN Program pre- and post-transition to SMOFlipid® from Intralipid® and to use demographic and clinical data to characterize possible patterns of change.

METHODS

Study population

- Adult patients who transitioned from Intralipid® to SMOFlipid® & were active in the BC HPN program between Jan. 1, 2013 to Oct. 31, 2017
- Convenience sampling was used (n=23)

Retrospective Chart Review

- Data recorded included:
 - Demographic & clinical characteristics
 - Monthly measurements of LFTs (serum alkaline phosphatase [ALP], alanine aminotransferase [ALT], aspartate aminotransferase [AST], Total Bilirubin) for the 6 months before and after transition to SMOFlipid®

Data analysis

- Descriptive statistics was used
 - Frequency and percentages for categorical variables
 - Mean (SD) for numerical variables; if data was largely skewed, median (IQR) used
 - Grand means for LFTs pre- & post-SMOFlipid® transition
- All analysis performed in Excel 2010

LFT Definitions

- Normal if fell within St. Paul's Hospital reference ranges:
 - AP: 30-105 U/L; ALT: 15-55 U/L; AST: 15-45 U/L; Total Bilirubin: <20 µmol/L
- Abnormal if levels are outside the reference range
- Severity based on degree of elevation⁷:
 - AP/ALT/AST: mild (<2x normal), moderate (2–5x normal), and severe (>5 times normal)
 - Total Bilirubin: mild (25.65–32.49 µmol/L), moderate (34.2–51.3 µmol/L), severe (>51.3 µmol/L)

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RESULTS

Table 1. Patient Characteristics at Date of Assessment

	(n = 10)
Age, years, mean ± SD	65.3 ± 8.58
Male/female, n	5/5
Weight, kg, mean ± SD	61.3 ± 12.52
BMI, kg/m², mean ± SD	21.79 ± 2.61
Presence of liver disease Yes/No, n	1/9
Presence of inflammatory bowel disease Yes/No, n	4/6
Indication for HPN SBS/Other, n	9/1
NPO/PO, n	1/9
Duration of parenteral nutrition at SMOF start date, d, median (IQR)	1512 (652.8-3858)

Table 2. HPN intake

	Intralipid® 20%, Mean ± SD	SMOFlipid® 20%, Mean ± SD
HPN calories (daily average), kcal,	1435.42 ± 391.62	1338.76 ± 458.85
Avg Lipid intake g/kg/d	0.59 ± 0.17	0.57 ± 0.17

Table 3. Grand mean of LFTs pre- and post-transition to SMOFlipid®

	Intralipid® 20%, Grand mean ± SD	SMOFlipid® 20%, Grand mean ± SD
ALP, U/L	341.44 ± 107.99	335.32 ± 119.04
ALT, U/L	60.1 ± 30.62	44.80 ± 16.24
AST, U/L	50.58 ± 14.96	38.07 ± 11.97
Total Bilirubin, µmol/L	15.84 ± 4.42	14.65 ± 6.38

Overall patterns of change pre- and post transition

KEY FINDINGS

- 19 patients constituted the study group
 - 6 patients did not have enough LFT measurements for meaningful analysis, 3 had outlier values
 - Therefore, analyzed sample = 10 patients
- Most demonstrated increases in all four LFTs in the 6 month period leading up to transition to SMOFlipid®
- After transition to SMOFlipid®, 70-80% of participants' LFTs showed a decrease in mean concentration
- Characteristics for a given pattern of change:
 - Decrease: more patients were women, had SBS, received HPN for 5+ years, and received ≥0.5 g/kg/d lipid from PN
 - Increase: patients (n=2) were over 70 years, had SBS, received HPN for <5 years, and received <0.5 g/kg/d lipid from PN

DISCUSSION AND CONCLUSION

- 50% of patients demonstrated liver injury while on Intralipid®, although none had a cholestatic pattern of injury⁷
- In general, LFTs declined after transition to SMOFlipid®, however the level of change and corresponding change in severity is variable
- Findings correspond with literature^{4-6, 8-10} regarding risk factors for hepatic dysfunction and effects of SMOFlipid® on LFTs
- The majority of studies comparing SO-based ILEs and mixed-lipid ILEs are done in acute and surgical settings⁴⁻⁶; our study is to our knowledge the first of its kind in the HPN population and looks at a transition between the two ILEs
- Our study did not correlate LFT improvement to SMOFlipid®

Study Limitations

- Small sample size
- Non-probability sampling
- Determining observed patterns of change subjective

Future Directions

- Larger sample size
- Longer term observation for more meaningful data
- Consider SMOFlipid® at baseline for HPN patients in order to reduce the risk of liver irritation or injury that may or may not be reversible

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