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Effect of alternative intravenous lipid emulsion in clinical outcome in non-critically ill patients

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SUMMARY

Introduction: Most studies on alternative intravenous lipid emulsion (IVLE) versus conventional IVLE have been conducted in the critically ill patients. The benefits of alternative IVLE in non-critically ill patients is uncertain. We aim to determine clinical outcome difference between alternative IVLE versus conventional IVLE in non-critically ill patients.

Method: All patients on parenteral nutrition (PN) from July 2007 to September 2010 were identified. Patients were stratified into two groups: conventional IVLE (soybean oil-based) and alternative IVLEs, namely MCT oil-based, olive oil-based and fish oil-containing IVLE.

Result: Three hundred and eighty-eight patients were included in the study. Ninety-one patients received soybean-based IVLE, 59 patients received MCT oil-based IVLE, 141 patients received olive oil-based IVLE and 97 patients received fish oil-containing IVLE. Adjusting the effect of baseline covariates in separate multiple linear/logistic regression models, there were no differences in mortality, readmission, length of stay and infection between conventional IVLE group and alternative IVLEs group, the adjusted p-value was 0.64, 0.06, 0.36 and 0.18 respectively. However, there was a significant change in day 5 CRP between these two groups (8.43 g/L (SD 112.2) vs −41.2 (SD 106.4); adjusted p-value = 0.01). There was no difference in day 5 albumin between these two group (−1.03 (SD 5.1) vs −0.1 (SD 5.3); adjusted p-value = 0.08).

Conclusion: Our study showed that pertinent clinical outcomes in non-critically ill patients who received either conventional IVLE or alternative IVLEs were the same. However, there was significant reduction in day-5 CRP in alternative IVLE compared to conventional IVLE.

1. Introductions

The conventional soybean oil-based IVLE is rich in long-chain triglycerides (LCT) and provides high percentage of linoleic acid (ω-6 PUFA). It is suggested that ω-6 PUFA may exaggerate inflammatory response and promote immunosuppressive effects, indirectly detrimental to the critically ill patients [1,2]. To overcome this, the use of alternative IVLEs such as medium chain triglycerides (MCT) and olive oil alone or in combination with soybean oil IVLE have been used to lower the content of ω-6 PUFA [14,15]. Fish-oil containing IVLE which provides large content of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) is speculated to provide anti-inflammatory effect has gained attention since its introduction in the 1990s [16,17]. Use of alternative IVLEs have been on the rise especially in Europe as recent studies have shown that alternative IVLE may improve clinical outcomes in the critically ill [3–5]. However the specific type of alternative IVLE is still debated.

The use of parenteral nutrition (PN) in the acute hospital setting does not confine only to critically ill patients. It is usually used as a

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last resort for feeding or a bridging therapy to enteral or oral feeding. PN has been instrumental as a source of nutrient in non-critically ill patients with acute reversible intestinal failure (type 1 and type 2 intestinal failures) who are still actively receiving medical and surgical-related treatment in general ward [6]. While the benefit of alternative IVLEs in critically ill patients is established, the benefit in non-critically ill patients, which constitute the majority of the PN recipients in the hospital, is less clear.

Non-critically ill patients are generally at a lower state of inflammation hence the potential benefit for attenuating inflammation by using alternative IVLE is theoretically less. However they represent a large proportion of patients receiving PN who often have complex medical problems and PN can be administered for long durations (between weeks to months). The combination of these factors, we believe, could lead to a significant clinical benefit through the provision of alternative IVLEs with lower ω-6 PUFA content.

The purpose of this study is to determine whether there is a difference in clinical outcome amongst non-critically ill patient who received conventional soybean oil IVLE versus alternative IVLE. In addition we will attempt to determine if there is a difference in the benefit provided by different types of IVLE by comparing conventional IVLE with three different types of alternative IVLE in non-critically ill patients receiving PN in an acute hospital setting. The primary outcome is to compare clinical outcomes which include mortality, readmission, infection rates and length of hospital stay (LOS) between conventional IVLE and alternative IVLEs.

2. Methods

We identified patients on PN from July 2007 to September 2010 at Singapore General Hospital from our prospectively collected database. The Institutional Review Board of our institution approved the study. By March 2008, soybean oil-based IVLE (Lipofundin-N 20%) supply had been ceased by the supplier to the country. This posed a unique opportunity for the hospital to utilize three other alternative IVLEs that were available in the country from April 2008 to September 2010 for the use of compounded PN bag in the hospital. The three alternative IVLEs were MCT oil-based (Lipofundin MCT/LCT 20%), olive oil-based (ClinOleic 20%) and contain fish oil (Lipidem).Only one alternative IVLE was utilised at a time for approximately nine or ten months before switching to another alternative IVLE in a consecutive manner. The sequence of alternative IVLE being used was MCT oil-based (Lipofundin MCT/LCT 20% for nine months), olive oil-based (ClinOleic 20% for ten months) and contain fish oil (Lipidem for ten months). By October 2010, only MCT-based oil (Lipofundin MCT/LCT) was used in the hospital after the company managed to attain a long term contract with the hospital. The component of each of the alternative IVLEs are listed in Table 1.

2.1. Patients

All patients received PN through a central venous access route after reviewed by the nutrition support team. The inclusion criteria were: Patients who were at least 18 years old, received PN for at least 5 days in general ward or high dependency unit (HDU), hemodynamic stable not requiring invasive/noninvasive ventilator support or inotropes support. Exclusion criteria included patients who received less than 5 days of PN, intensive care unit (ICU) patients, PN started in ICU and continue in general ward or HDU, PN restarted in less than 3 days after receiving PN in ICU, patient on invasive/non-invasive ventilator support or inotropes support and home PN patients.

Table 1
Types of IVLE and its composition.

IVLE type	Commercial name	Composition
Soybean oil-based (Type 1)	Lipofundin-N 20%	100% SO
MCT oil-based (Type 2)	Lipofundin MCT/LCT 20%	50% MCT 50% SO
Olive oil-based (Type 3)	ClinOleic	80% OO 20% SO
FO-containing (Type 4)	Lipidem	50% MCT 40% LCT 10% FO

SO- soybean oil; MCT-medium chain triglycerides; LCT-long chain triglycerides; OO-olive oil; FO-fish oil.

2.2. Parental nutrition formulation

All parental nutrition was formulated according to a standardized protocol by hospital nutrition support team. Three pharmacists in the team who received similar training on PN prescribed all PN. For patients who were at risk of refeeding syndrome, initial calorie prescribed started at 10 kcal/kg/day and slowly up-titrate to target calorie of 25 kcal–30 kcal/kg/day. Protein prescription varies according to the patient's presentation. The protein of 0.8–2.0 g/kg/day was prescribed. No immunonutrition was prescribed. All electrolytes were checked daily on the first three days of PN and any abnormalities were replaced accordingly. Lipid and liver panel were checked on the first day of initiation and once a week while on PN. Central lines were removed when line sepsis was suspected.

2.3. Outcomes

Mortality was defined as death during hospitalization and within 30 days of discharge. Mortality occurred within 30 days of discharge would be recorded from the hospital electronic medical record. Readmission was defined as patients who were initially discharged but readmitted to the hospital within 30 days of discharge. Length of stay was calculated by excluding patient who passed away during the study period. Patients who passed away during the study period were not included in the readmission analysis. Infection is defined as any positive culture (blood/line/bodily fluid) and radiology imaging suggestive of infection (abscess/consolidation/collection) after 24 h of starting PN. Change in day-5 CRP and albumin were performed by subtracting day-5 of CRP and albumin value from day-1 CRP and albumin value, respectively.

2.4. Statistics

Demographic and baseline characteristics were compared using ANOVA continuous variable whereas the Chi–Square test was used for categorical variables. For continuous variables, the mean and standard deviation were provided. Percentages were given for categorical variables. P-value $\leq$ 0.05 was considered statistically significant. A t-test was used to compare the length of stay (in log-scale) among two groups whereas an ANOVA was used for more than two groups' comparison. Clinical outcomes were first analysed between conventional IVLE and alternative IVLE as a group. We conducted multiple linear/logistic regressions to adjust the effect of baseline covariates in the relationship of different outcome variables with binary types of IVLE.

3. Results

537 patients were started on PN and 388 patients were included in the study (Fig. 1). 149 patients were excluded from the study. 64 patients with incomplete data, 47 patients received less than 5 days of PN, 35 patients started PN in intensive care unit (ICU), 2 home PN patients and 1 patients had triglyceride > 5 mmol/l 91 patients

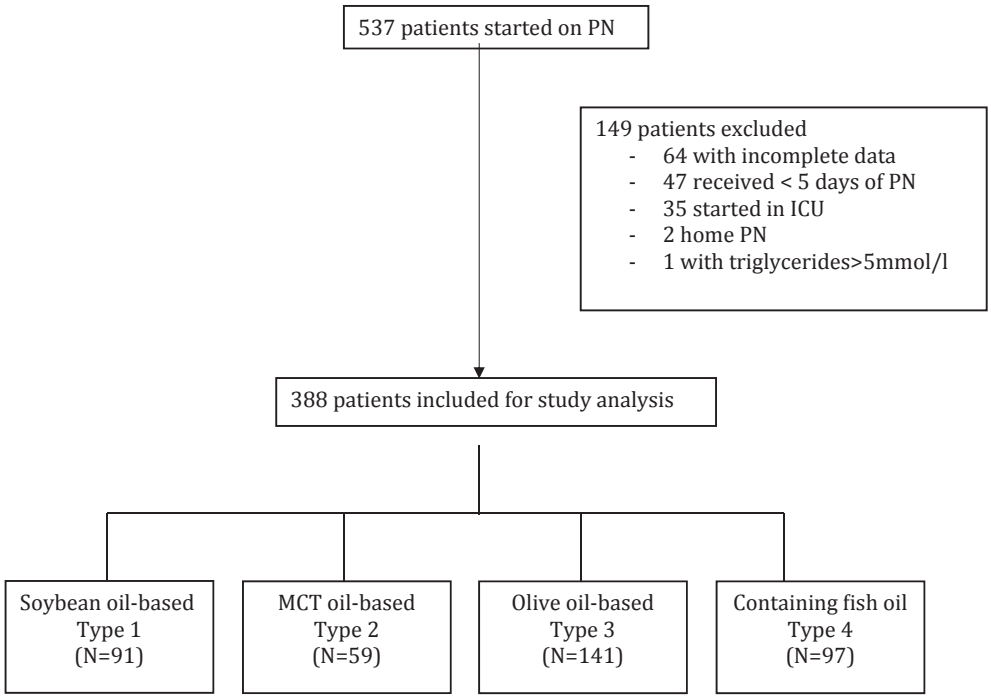

Fig. 1. Consort diagram of patient populations on parenteral nutrition (PN). ICU, intensive care unit.

were on soybean-based IVLE, 59 patients were on MCT oil-based IVLE, 141 patients were on olive oil-based IVLE and 97 patients were on IVLE containing fish oil.

3.1. Clinical characteristic of patients

Baseline characteristic between conventional and alternative IVLEs as a group were almost similar (Table 2). Baseline albumin in alternative IVLEs were higher but not clinically significant (24.4 vs 23.9, $p = 0.05$). Majority of the patients who received PN were surgical patients. Surgical indication for PN commencement included significant ileus post operation, complete bowel obstruction, high enterocutanous fistula output and severely malnourished patient and for which enteral nutrition alone was unable to maintain requirement before the operation. Majority of the medical condition were oncology-related which included severe mucositis following chemotherapy and bowel rest following a diagnosis of aggressive gastrointestinal lymphoma.

3.2. Clinical outcomes

3.2.1. Conventional IVLE vs alternative IVLE as a group

Hospital LOS was significantly lower in alternative IVLEs as a group versus conventional IVLE (33.5 days (SD = 20.8) vs 41.4 days (SD = 25.9); $p = 0.02$). However, when we use a multiple linear regression model to adjust the effect of the baseline covariates, the LOS between the groups were not significantly different with an adjusted p-value of 0.36. There were no differences in mortality, readmission and infection rates between conventional and alternative IVLEs as a group (Table 3).

There was a significant reduction in day-5 CRP in the alternative IVLE group versus conventional group (−41.2 (106.3) vs 8.4 (112.2) adjusted $p = 0.01$) but no difference in albumin (−0.1 (SD = 5.3) vs −1.03 (SD = 5.1); $p = 0.08$).

3.3. Clinical outcomes of each IVLE

Subsequent clinical outcome analysis was performed for conventional IVLE versus each alternative IVLE (Table 4). No statistically difference in mortality, readmission and infection rates between conventional IVLE and each of the alternative IVLEs.

3.4. Controlling false discovery rate

We have calculated q-values (using unadjusted p-values) to control the false discovery rate corresponding to 10 different hypotheses in Tables 2 and 3 As is evident from Table 2, that q-value corresponding to the length of stay is 0.07, which is above 0.05 but less than 0.1 level. On the other hand, in Table 2, the q-value corresponding to change in day 5 CRP is 0.01, indicating a significant change in CRP values from day 1 to day 5 even after controlling for false discovery rate.

4. Discussion

We found that the clinical outcomes between alternative IVLE and conventional IVLE were the same. At first, without adjusting the baseline covariates, the LOS was significantly lower in alternative IVLEs as a group compared to conventional IVLE (p-value = 0.02). The mean LOS was 7.9 days (19%) shorter in patients who received alternative IVLEs. However after using multiple linear regression models to adjust the effect of the baseline covariates the p-value was no longer significant which suggest that apparent effect of lower LOS for the alternative IVLE (as a group) compare to conventional IVLE was due to differences in baseline covariates in the two groups. Our findings were similar to a retrospective study examining 30-day mortality and LOS in a mixed heterogeneous group of patients of both critically ill and non-critically ill patients receiving either olive oil-based IVLE or conventional IVLE [14]. However the

Table 2
Demographics and patient's characteristic of soybean oil versus alternative IVLE as a group and versus each of the IVLE.

Variables	IVLE						
	Soybean oil (Type 1)	Alternative IVLE (As a group)	P Value	MCT oil (Type 2)	Olive oil (Type 3)	Fish oil (Type 4)	P Value
No. of Patients (N)	91	297	–	59	141	97	–
Age Mean (SD)	58.0 (16.1)	58.6 (15.7)	0.77	60.0 (12.6)	58.0 (16.4)	58.5 (16.3)	0.87
Gender (% male)	53.9	57.2	0.75	49.2	60.3	57.7	0.73
Ethnicity (%)							
Chinese	82.4	78.5		74.6	84.4	72.2	
Malay	8.8	12.5		13.6	9.9	15.5	
Indian	3.3	2.0	0.74	3.4	0.0	4.1	0.47
Others	5.5	7.1		8.5	5.7	8.3	
TPN duration Mean (SD)	17.2 (15.5)	15.5 (13.8)	0.33	17.8 (18.9)	14.8 (11.9)	15.0 (12.7)	0.38
Admission under							
Medical (N,%)	21 (23.1)	29 (19.9)		12 (20.3)	30 (21.2)	17 (17.5)	0.85
Surgical (N,%)	70 (76.9)	238 (80.3)	0.61	47 (79.7)	111 (78.8)	80 (82.5)	
ICU admission before PN commencement (N,%)	3 (3.3)	18 (6.1)	0.45	5 (8.5)	11 (7.8)	2 (2.1)	0.13
Baseline CRP (mg/L) Mean (SD)	89.7 (92.6)	97.9 (88.6)	0.48	108.3 (85.9)	89.8 (83.1)	104.0 (99.3)	0.49
Baseline albumin (g/L) Mean (SD)	23.9 (6.8)	24.4 (6.8)	0.05	23.3 (7.4)	23.8 (6.3)	26.0 (6.9)	0.03
Body mass index Kg/m^2 Mean (SD)	20.8 (3.5)	20.9 (4.1)	0.93	21.0 (4.6)	20.6 (3.8)	21.2 (4.1)	0.80
Total calorie Mean (SD)	1152.3 (257.8)	1152 (258.0)	0.99	1145.3 (203.7)	1155.9 (269.9)	1153.1 (277.4)	1.00
Calorie/kg/day Mean (SD)	21.2 (4.2)	21.4 (3.4)	0.71	21.8 (3.4)	21.5 (3.5)	20.9 (3.3)	0.46
Protein/kg/day	0.97 (0.18)	0.98 (0.15)	0.86	0.96 (0.15)	0.98 (0.14)	0.98 (0.15)	0.76

Table 3
Comparison of clinical outcomes Soybean oil with alternative IVLE as a group.

	Types of IVLE			q-value (controlling false discovery rate)	p-value (baseline covariate adjusted)
	Soybean oil	Alternative IVLE (as a group)	p-value		
Mortality % (N)	23.7 (21)	16.5 (49)	0.16	0.23	0.64
Readmission % (N)	17.1 (12)	21.9 (65)	0.15	0.23	0.06
Length of stay Mean (SD) in days	41.4 (25.9)	33.5 (20.8)	0.02	0.07	0.36
Infection % (N)	45.1 (41)	42.4 (126)	0.72	0.72	0.18
Change in Day 5 CRP Mean (SD)	8.43 (112.2)	−41.2 (106.4)	0.001	0.01	0.01
Change in Day 5 albumin Mean (SD)	−1.03 (5.1)	−0.1 (5.3)	0.13	0.23	0.08

Table 4
Comparison of four types of IVLE.

	Types of IVLE					q-value (controlling false discovery rate)
	Soybean oil	MCT oil	Olive oil	Fish oil	p-value	
Mortality % (N)	23.7 (21)	18.6 (11)	17.7 (25)	13.4 (13)	0.40	0.50
Readmission % (N)	17.1 (12)	16.7 (8)	27.6 (32)	29.8 (25)	0.10	0.23
Length of stay Mean (SD) in days	41.4 (25.9)	38.0 (23.0)	32.6 (19.6)	32.1 (20.9)	0.02	0.07
Infection % (N)	45.1 (41)	50.8 (30)	41.8 (59)	38.1 (37)	0.58	0.64

infection rate was reported higher in the olive oil-based IVLE in the same study likely due to higher proportion of their patients who received olive oil-based IVLE were admitted to ICU had a longer ICU stay which predisposed them to nosocomial infection.

Our study is novel in evaluating the clinical outcomes of non-critically ill patients on PN, an understudied area of great clinical significance because it represents the majority of the hospital patients on PN. While the use of soybean oil-sparing strategy has been proposed to improve clinical outcome by attenuating the proinflammatory cytokines in critically ill patients [9,10], the benefit in non-critically ill patient is uncertain. Similar to studies involving critically ill patients, we found no mortality difference between conventional IVLE and alternative IVLE despite a significant greater reduction in day-5 CRP in alternative IVLE in our cohort and also a theoretical reduction in proinflammatory profile [3,5]. This is probably because mortality is an infrequent event in non-critically ill patients and our sample is underpowered to detect any significant difference [7,8]. Higher reduction in day-5 CRP observed in alternative IVLEs group is likely due to its theoretical inflammatory neutral and anti-inflammatory properties of these newer generation IVLEs [16,18] .

In our study, the infection rates were similar between the alternative and conventional IVLEs as a group. Outcomes of infection rates in previous studies on the use of alternative IVLEs in both critically ill and non-critically ill patients had been mixed [11,14]. Although fish oil-containing IVLE has been shown to reduce infection rate in the critically ill patients in a recent systematic review by Manzanares et al., our study did not show any infection rate difference between fish oil-containing IVLE and the conventional IVLE [4].This could be because patients in our cohort were relatively more stable, hence one may extrapolate that they have lower proinflammatory cytokines such that the benefit of further attenuation of these cytokines by alternative IVLE had no significant impact on the infection rates.

This is a retrospective cohort study, hence is susceptible to confounders as such as heterogeneity of the patient populations, changing surgical techniques and clinical practice over time. Our cohort received less than the recommended total calorie and protein intake across all groups, which reflect a common 'real-world' issue that adherence to recommended intake, may be impossible due to delivery factor (delays/interruption), patient's factor and clinical preference [12,13]. Ideally, we would like to do perform propensity score-based match of patients but due to a bigger number of patients in alternative IVLEs compared to conventional IVLE (297 cases vs 91 cases), we do not have enough controls that can be matched with cases. Hence we conducted multiple linear/logistic regressions to adjust the effect of baseline covariates in the relationship of different outcome variables with binary types of IVLE in Table 3. In addition, we did not have nutrition marker such as handgrip strength, weight change or subjective global assessment to compare pre-and post-nutrition intervention. Nonetheless, the similar baseline patient clinical characteristics among our treatment groups and standardization of PN protocol as well as clearly defined clinical outcomes would go some way in mitigating these weaknesses.

The results of this study add to the body of evidence suggesting that alternative IVLEs are not only safe to use in critically ill patients but also in non-critically ill patients in acute hospital setting. It also showed that alternative IVLEs is associated towards greater CRP reduction. Future prospective randomized studies are needed to confirm this finding.

Conflict of interest

All authors declare there is no conflict of interest.

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Author contribution statement

Research Design: LKL, WYT.
Data Collection: ES, VT, TP, TLB, PBY, JC, LKL, BHL, NHM.
Statistical analysis: PG, WYT.
Paper writing: ES, WYT.
Supervision: WYT.
Critique and review of the final manuscript: ES,VT,TP,TLB, PBY,JC,LKL,BHL,NHM,PG,LKL,WYT.

CRediT authorship contribution statement

Ennaliza Salazar: Investigation, Project administration, Data curation, Writing - original draft, Writing - review & editing. **Palash Ghosh:** Formal analysis, Writing - review & editing. **Victor Tan:** Investigation, Data curation. **Tamara Pang:** Data curation. **Bee Yen Poh:** Project administration, Data curation. **Lee Boo Tan:** Project administration, Data curation. **Kia Lan Loy:** Project administration, Data curation. **Janet Chong:** Project administration, Data curation. **Ho Man Ng:** Project administration, Data curation. **K.L. Ling:** Visualization, Resources. **Y.T. Wang:** Visualization, Resources, Investigation, Validation, Writing - review & editing.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.clnesp.2019.07.013.

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