Original Article

Structured triglyceride for parenteral nutrition: meta-analysis of randomized controlled trials

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This study assessed the safety and efficacy of structured triglyceride (ST) for parenteral nutrition. A meta-analysis of all the relevant randomized controlled trials (RCTs) was performed. Clinical trials were identified from the following electronic databases: MEDLINE, EMBASE, the Cochrane Controlled Trials Register, Chinese Bio-medicine Database. The search was undertaken in March 2005. Language was restricted to Chinese and English. Literature references were checked at the same time. Only RCTs were extracted and evaluated by two reviewers independently of each other. The statistical analysis was performed by RevMan4.2 software which was provided by the Cochrane Collaboration. A *P* value of <0.05 was considered statistically significant. Ten RCTs involving 236 patients were included. Eight of them compared ST with the long-chain triglyceride (LCT), and the combined results showed that the ST had significant effect on resting energy expenditure (weighted mean difference [WMD] = 1.54, 95%CI [1.26, 1.82], *P*<0.00001), plasma glycerol (WMD = 0.14, 95%CI [0.06, 0.22], *P*=0.0007), free fatty acids (WMD = 0.24, 95%CI [0.10, 0.37], *P*=0.0006), and β-hydroxybutyric acid (WMD = 0.14, 95%CI [0.06, 0.22], *P*=0.0007), but no differences was found regarding nitrogen balance (standardized mean difference [SMD] = 0.64, 95%CI [-0.30, 1.59], *P*= 0.18), respiratory quotient (WMD = -0.02, 95%CI [-0.04, 0.01], *P*=0.18), and plasma triglycerides (WMD = -0.10, 95%CI [-0.30, 0.10], P=0.32). Only two RCTs compared ST with the physical mixture of medium- and long-chain triglyceride (MCT/LCT), data from trials were not combined due to clinical differences between trials, and conclusions can not be drew from the present data. ST appeared to be safe and well tolerated. Further trials are required, especially compared with the MCT/LCT, with sufficient size and rigorous design.

Key Words: structured triglyceride, parenteral nutrition, meta-analysis, randomized controlled trials.

Introduction

Fat emulsions are an important component of parenteral nutrition (PN). They supply energy and essential fatty acids. Fat emulsions containing long-chain triglycerides (LCT) are the most widely used fats in PN, but only half of these LCTs are immediately metabolized for energy production, the rest being stored in adipose tissue. Furthermore, the use of LCT may induce immunologic and metabolic side effects.[1,2] Fat emulsions containing medium chain triglycerides (MCT) have been proposed for PN since MCT is hydrolyzed twice as fast as LCT and the resulting medium chain fatty acids (MCFA) are oxidised more raidly and more completely than long chain fatty acids (LCFA).[3,4] But a pure MCT emulsion may cause metabolic acidosis, neurologic side effects, increased energy expenditure, and essential fatty acid deficiencies.[5-7] To reduce the amount of MCFA and to provide the essential LCFA, the MCT are administered together with LCT, as a physical mixture (MCT/LCT). MCT/LCT emulsions have been suggested as an alternative energy source because of a partially non-carnitine-dependent transport into the mitochondria with a higher oxidation rate, a faster plasma clearance, and a decreased tendency to accumulate in the reticuloendothelial system.[8, 9]

To improve the safety of MCT, a structured triglyceride (ST) emulsion containing both MCFA and LCFA bound on the same glycerol backbone was developed. This structured molecule was designed to utilise the positive effects of MCFA while circumventing the side effects. ST has been well accepted as a fuel source for enteral nutrition.[10, 11] Is it also safe and efficacious for PN? Some trials have shown its safety and efficacy for PN.[12-30] However, most of these studies were of small to moderate sample sizes, and thus the clinical effectiveness of ST is not accepted throughout the medical community. In this meta-analysis, we assessed its safety and efficacy for PN.

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Methods

Materials

Randomized controlled trials (RCTs) of ST for PN were included in this meta-analysis. Language was restricted to Chinese and English.

Search strategy

Search was applied to the following electronic databases: the Cochrane Library (2005.3), MEDLINE (1966-2005.3), EMBASE (1980-2005.3) and Chinese Biomedicine Database (1979-2005.3). Literature reference proceedings were handsearched at the same time. The searching words were structured triglyceride.

Selection

Inclusion criteria

The initial inclusion criteria were (1) randomized controlled trials (RCT) regardless of whether they were single blind, double blind or not blinded; (2) the treatment group receiving ST for PN; and (3) inclusion of a parallel control group receiving LCT or MCT/LCT for PN.

Exclusion criteria

Studies that met the initial inclusion criteria were then further examined. Studies with duplicate publication, unbalanced matching, only abstract or incomplete data were excluded. When duplication occurred, the studies reported in conference proceedings, in earlier publications were excluded.

Data collection and analysis

Data were extracted independently by two reviewers according to the prespecified selection criteria. Disagreement was resolved by discussion. The following data were extracted: the baseline of trials; nitrogen balance, resting energy expenditure (REE), respiratory quotient (RQ), triglycerides, glycerol, free fatty acides, β-Hydroxybutyric acid; the adverse events; the statistical consideration. Methodological quality was evaluated using the Jadad scale, based on randomization, double blinding, and withdrawals/dropouts.[31] The scores range from one to five, one or two being considered as low quality, and three to five as high quality. In addition, concealment of the generated random allocation sequence was scored by the criteria adopted from The Cochrane Handbook.

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Results

There were 1128 papers relevant to the searching words. Through the steps of screening the title, reading the abstract and the entire article, ten RCTs involving 236 patients were included.[12-21] Characteristics of studies included in meta-analysis of ST for PN is presented in Table 1. The ST group received ST 73403 (Fresenius Kabi AB, Sweden) or Structolipid (Fresenius Kabi AB, Sweden). This emulsion contains fractionated interesterified triglycerides with both MCFA and LCFA bound to the same glycerol backbone. The LCT group received Intralipid (Fresenius Kabi AB, Sweden) which contains 100% LCT from fractionated soybean oil. The MCT/LCT group received Medialipide (B. Braun, Boulogne, France) or Lipofundin (B. Braun, Melsungen AG, Germany). The MCT are administered together with LCT, as a physical mixture.

Eight of them compared ST with the LCT, and the combined results showed that the ST had significant effect on REE (WMD=1.54,95%CI [1.26,1.82], $P<$ 0.00001), plasma glycerol (WMD = 0.14, 95%CI [0.06, 0.22], P=0.0007), free fatty acids (WMD = 0.24, 95%CI [0.10, 0.37], P=0.0006), and β-hydroxybutyric acid (WMD = 0.14, 95%CI [0.06, 0.22], P=0.0007), but no differences was found regarding nitrogen balance (SMD = 0.64, 95%CI [-0.30, 1.59], P= 0.18), RQ (WMD = -0.02, 95% CI [-0.04, 0.01], P=0.18), and plasma triglycerides

Table 1. Characteristics of studies included in meta-analysis of structured triglyceride for parenteral nutrition.

Author	Year	Country	Study design	ST	Control	Cases	Age (Years)	Sex (M/F)	Weight (kg)	Jadad Score
Sandstrom	1993	Sweden	DB,RCT	73403	Intralipid	20	65	13/7	70	4
Nordenstrom	1995	Sweden	CO,RCT	73403	Intralipid	9	29	9/0	75	2
Sandstrom	1995	Sweden	CO,DB,RCT	73403	Intralipid	37	64	28/9	68	3
Chambrier	1999	France	DB,RCT	73403	Medialipide	40	61	27/11	70	3
Bellantone	1999	Italy	DB,RCT	73403	Intralipid	19	60.5	9/10	66.4	3
Wu	1999	China	CO,RCT	Structolipid	Intralipid	16	54	*	71	2
Wu	2000	China	CO,RCT	Structolipid	Intralipid	16	35	*	72	2
Rubin	2000	Israel	CO,DB,RCT	Structolipid	Intralipid	22	43.3	14/8	53.9	4
Lindgren	2001	Sweden	DB,RCT	Structolipid	Intralipid	30	55.9	16/4	*	4
Kruimel	2001	Sweden	DB,RCT	Structolipid	Lipofundin	27	68	20/5	71	4

Abbreviations: RCT, randomized controlled trial; CO, cross-over; DB, double-blind; ST, structured triglyceride; M/F, Male/Female; * No data available.

Table 2. Results from meta-analysis of structured triglyceride for parenteral nutrition compared with long-chain triglyceride

Outcome	Studies	Participants	Statistical method	Effect size (95% CI)	*P*
Resting energy expenditure	4	114	WMD (fixed)	1.54 [1.26, 1.82]	< 0.00001
Plasma glycerol	5	140	WMD (random)	0.14 [0.06, 0.22]	0.0007
Free fatty acids	8	212	WMD (random)	0.24 [0.10, 0.37]	0.0006
β-hydroxybutyric acid	7	172	WMD (random)	0.14 [0.06, 0.22]	0.0007
Nitrogen balance	5	133	SMD (random)	0.64 [-0.30, 1.59]	0.18
Respiratory quotient	4	114	WMD (random)	-0.02 [-0.04, 0.01]	0.18
Plasma triglycerides	7	172	WMD (random)	-0.10 [-0.30, 0.10]	0.32

Abbreviations: WMD, weighted mean difference; SMD, standardized mean difference; CI, confidence intervals.

(WMD = -0.10, 95%CI [-0.30, 0.10], *P*=0.32). The results are presented in Table 2. Only two RCTs compared ST with MCT/LCT, data from trials were not combined due to clinical differences between trials, and conclusions can not be drew from the present data. All trials detailed the clinical and laboratory safety assessments. ST appeared to be safe and well tolerated. None of the proposed side effects for the ST were observed. All clinical adverse events were considered as being unlikely to have been related to the lipid emulsion treatment.

Discussion

ST for PN in this meta-analysis, ST 73403 (Fresenius Kabi AB, Sweden) or Structolipid (Fresenius Kabi AB, Sweden), is an interesterified mixture of equimolar amounts of LCT and MCT, corresponding to 64% (w/w) and 36% (w/w), respectively. The fatty acids are randomly distributed within the interesterified triglyceride molecule. ST consists mainly of mixed chain triglycerides, i.e. containing medium as well as long chain fatty acids (approx 75%) with minor proportions of LCT and MCT. MCT is a synthetic oil originated from coco-nut oil and/or palm kernel oil and LCT is added in the form of refined soybean oil. Figure 1 shows the molecular structure of MCT, LCT, and ST.[21]

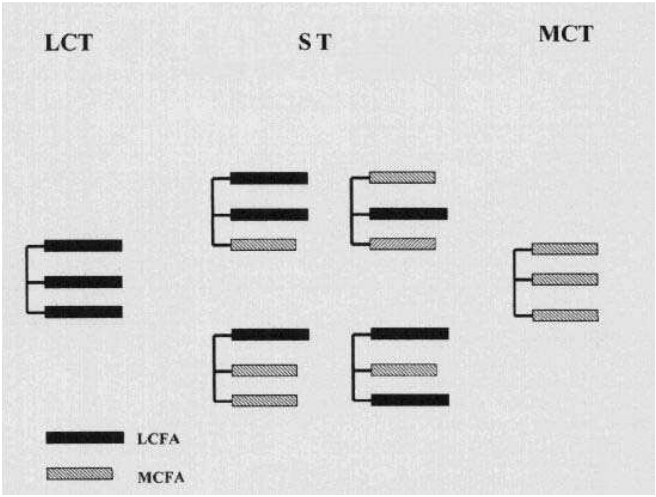

Figure 1. The molecular structure of long-chain triglycerides (LCT), structured triglycerides (ST), and medium-chain triglycerides (MCT).

In humans, this meta-analysis demonstrates that ST is safe and well tolerated. None of the proposed side effects for the ST were observed. Similarly, preclinial safety studies with ST (73403) on acute toxicity in mice and rats; on tolerance in rats (at 14 and 28 days) and in dogs (at 8 days, 1 months, and 3 months); on cardiovascular effects in cats; and on climination rate in rabbits have been carried out and have suggested that ST (73403) is rapidly metabolized and is climinated more rapidly than Intralipid.[32] Reproduction studies have been performed with satisfactory results.[33]

Nitrogen balance studies are widely used as an index of effectiveness of nutrition support. In rats, ST has been reported to have positive effects on nitrogen balance, weight gain, and protein kinetics when compared with emulsions containing only LCT or MCT/LCT.[34,35] However, in our meta-analysis, no differences were found in nitrogen balance. The result must be interpreted with small sample size, the difference in patients, and heteroeneity. ST increased REE significantly when compared to LCT. This suggested increased fat oxidation during infusion of a ST emulsion when compared to infusions of a LCT emulsion. But there was no statistically significant difference between the ST and LCT emulsions with respect to RQ. This may be explained by the fact that indirect calorimetry cannot detect small changes in substrate oxidation. The difference in results between studies might be due to different patient populations, dose of fat emulsion or differences in energy, fat and carbohydrate intake.

ST increased β-hydroxybutyric acid significantly when compared to LCT. MCFA are ketogenic in contrast to LCFA[6,7] and ketone bodies have been demonstrated to increase protein synthesis when administered both in humans and in dogs.[36-38] The infusion of Na-D-β-hydroxybutyrate increased insulin secretion since the plasma C-peptide concentrations were significantly increased and insulin could induce changes in hepatic protein synthesis. MCT and MCT/LCT emulsions can cause metabolic acidosis when infused intravenously, as a result of rapid MCFA metabolism. Moyer *et al*., evaluates the effect of three different MCT-containing lipid emulsions (MCT, MCT/LCT, ST) on acid-base balance. They found a reduced risk of metabolic acidosis in dogs receiving the ST. In contrast to MCT or MCT/LCT, ST may constitute a safer method of providing MCFA, as the kinetics of octanoate (C8) in the ST is altered, compared to MCT/LCT, resulting in a slower and therefore more balanced metabolism.[39]

The clearance and oxidation of ST was faster compared with LCT in fasted unanesthetized rats by the study of Hultin *et al*.[40] The hypothesis was also confirmed by this meta-analysis. The clearance rate of an emulsion from the blood is intrinsic to the relationship between the physicochemical properties of the emulsion droplets and a physiological response by the reticuloendothelial system (RES). Small emulsion particles are removed slower than larger droplets, and negatively or positively charged emulsified particles are removed quickly in comparison to neutral emulsion droplets. In conclusion, based on the meta-analysis, ST appeared to be safe and well tolerated. Further trials are required, especially compared with the MCT/LCT, with sufficient size and rigorous design.

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Original Article

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结构甘油三酯与肠外营养：随机对照试验的元分析

本研究评价了结构甘油三酯对肠外营养的安全性和有效性，对所有相关的随机对照试验(RCTs)进行了元分析。元分析所涉及到的临床研究是从 MEDLINE, EMBASE, the Cochrane Controlled Trials Register, 中国生物医学数据库（Chinese Bio-medicine Database）等电子数据库里筛选得到的。于 2005 年三月进行文献检索，检索的文献语言类型限为英语和汉语，同时检查搜索到文献的参考文献。仅仅筛选随机对照试验，由两个互不干扰的校阅者评价挑选。采用 Cochrane 公司提供的 RevMan4.2 软件包进行统计分析，P <0.05 视为显著性差异。元分析共包括十个 RCTs，涉及到 236 病人。十个 RCTs 中有八个比较了结构甘油三酯与长链甘油三酯(LCT)，这些研究结果表明结构甘油三酯对静息能量消耗(加权平均差[WMD] = 1.54, 95%CI [1.26, 1.82], P<0.00001)、血浆甘油(WMD = 0.14, 95%CI [0.06, 0.22], P=0.0007)、游离脂肪酸(WMD = 0.24, 95%CI [0.10, 0.37], P=0.0006)和 β-羟丁酸 (WMD = 0.14, 95%CI [0.06, 0.22], P=0.0007)有显著的影响，但两者氮平衡（标准平均差[SMD] = 0.64, 95%CI [-0.30, 1.59], P= 0.18）、呼吸系数(WMD = -0.02, 95%CI [-0.04, 0.01], P=0.18)、和血浆甘油三酯(WMD = -0.10, 95%CI [-0.30, 0.10]P=0.32)之间并没有差异。只有两个 RCTs 比较了结构甘油三酯与中链，长链甘油三酯的混和物(MCT/LCT)，由于研究间存在的临床差异而没有把这两个研究的数据结合起来分析，以目前的研究数据也不能得出结论。结构甘油三酯对人体似乎是安全的，人体也具有很好的耐受性。但这仍需进一步进行样本量足够的，设计严格的临床研究，特别是进行与 MCT/LCT 比较的研究来证实。

关键词：结构甘油三酯、肠外营养、元分析、随机对照试验。