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


CRD summary
The authors aimed to assess the efficacy and safety of structured triglyceride (ST) for parenteral nutrition. They concluded that ST appears safe and well-tolerated, but did not reach a clear conclusion on its efficacy. Methodological limitations and poor reporting in the review mean that their conclusion that ST is safe may not be reliable.

Authors' objectives
To assess the efficacy and safety of structured triglyceride (ST) for parenteral nutrition.

Searching
MEDLINE, EMBASE, the Cochrane CENTRAL Register and the Chinese Biomedical Database were searched to March 2005 on the term 'structured triglyceride'. The reference lists of relevant articles were also checked. The search was limited to studies published in full in English or Chinese.

Study selection
Parallel-group randomised controlled trials (RCTs) were eligible for inclusion. The review also included crossover studies. Studies with baseline inequalities were excluded. Eligible studies compared ST with long-chain triglyceride (LCT) or medium-chain triglyceride/long-chain triglyceride (MCT/LCT) emulsion for parenteral nutrition. The interventions in the included studies comprised different types of ST (ST 73403 and Structolipid), while control interventions comprised LTC (Intralipid) or MCT/LCT (Medialipide or Lipofundin). No inclusion criteria were specified for the participants. The participants in the included studies were men and women aged 29 to 68 years and weighing 53.9 to 75 kg, where reported. No inclusion criteria were specified for the outcomes. The review reported resting energy expenditure (REE), plasma glycerol, free fatty acids, β-hydroxybutyric acid, nitrogen balance, respiratory quotient and plasma triglycerides.

Two reviewers independently selected studies for the review. It was not stated how any disagreements were resolved.

Assessment of study quality
The included studies were assessed for risk of bias (by evaluating allocation concealment) and also by using the Jadad scale, which measures adequacy of randomisation, blinding, and the management of withdrawals and drop-outs. Each study was awarded a score out of a maximum of 5 points; a score of 1 to 2 points indicated low quality, while a score of 3 to 5 points indicated high quality.

Two reviewers independently conducted the validity assessment. It was not stated how any disagreements were resolved.

Data extraction
Two reviewers independently extracted mean differences between the groups in each study. Any disagreements were resolved by discussion.

Methods of synthesis
The studies were combined using random-effects or fixed-effect models to calculate standardised or weighted mean differences (WMDs) with 95% confidence intervals (CIs). The χ² test was used to evaluate statistical heterogeneity. A random-effects model was used where there was significant heterogeneity (p<0.1).

Results of the review
Ten RCTs (n=236) were included, of which 5 were crossover studies (n=100).
Seven RCTs (n=177) were double-blinded. The Jadad scores ranged from 2 to 4.

There were 8 studies of ST versus LCT. Compared with the LCT group, the ST group had a significantly higher levels of REE (WMD 1.54, 95% CI: 1.26, 1.82, p<0.00001; 4 RCTs) and significantly lower levels of plasma glycerol (WMD 0.14, 95% CI: 0.06, 0.22, p=0.0007; 5 RCTs), free fatty acids (WMD 0.24, 95% CI: 0.10, 0.37, p=0.0006; 8 RCTs) and β-hydroxybutyric acid (WMD 0.14, 95% CI: 0.06, 0.22, p=0.0007; 7 RCTs). There was no statistically significant difference between the groups for nitrogen balance (5 RCTs), respiratory quotient (4 RCTs) and plasma triglycerides (7 RCTs). Random-effects models were used for all outcomes except REE.

There were 2 studies of ST versus MCT/LCT. The studies were clinically heterogeneous and inconclusive, and data were not reported in the review.

All studies gave details of clinical and laboratory safety assessments. No clinical adverse effects were considered likely to be treatment related.

Authors' conclusions
ST appears to be safe and well-tolerated and has a statistically significant effect on REE, plasma glycerol, free fatty acids and β-hydroxybutyric acid compared with LCT.

CRD commentary
The review question was clear, but the inclusion criteria were poorly defined and did not specify the participants or outcomes of interest, which made the findings difficult to interpret. The search apparently utilised only one search term and was limited to studies published in English or Chinese, which means that some studies might have been missed. Steps were taken to minimise the risk of error or bias in the review process by having two reviewers independently make decisions on study validity and data extraction, but it is unclear whether this also applied to the study selection stage. The information about the included studies was inadequate (e.g. there were insufficient details on allocation concealment, study setting and outcome measures for adverse effects). Statistical heterogeneity was considered in the choice of statistical model but was not quantified in the text. The authors did not reach any clear conclusion about the efficacy of ST, and they provided inadequate data about adverse effects to support their conclusion that ST is safe.

Implications of the review for practice and research
Practice: The authors stated that ST appears safe and well-tolerated.

Research: The authors stated that further trials are required, in particular comparing ST with MCT/LCT.

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