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SHARING EXPERTISE

Influence of Lipoplus®/Lipidem® fat emulsion on postoperative nutritional status and early inflammatory response in patients with gastrointestinal malignancies

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OBJECTIVE

To investigate the effect of Lipoplus®/Lipidem® on postoperative nutritional status and early inflammatory response in patients with gastrointestinal malignancies.

RESULTS

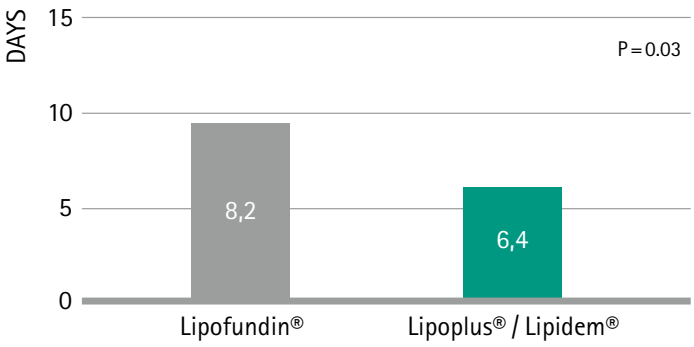
On postoperative day 1, prealbumin and retinol binding protein were significantly lower as compared to preoperative levels for patients in both groups.

These parameters were significantly ($P<0.05$) elevated on postoperative day 6 and a normal nitrogen balance had been reached. On postoperative day 6, CRP was significantly lower in both groups as compared to postoperative day 3 ($P<0.05$), and the decreasing trend in the Lipoplus®/Lipidem® group was more significant ($P<0.05$) than in the Lipofundin® group.

There was a significant increase in LTB5/LTB4 as compared to postoperative day 1 ($P<0.05$) in the Lipoplus®/Lipidem® group, however the increase was not statistically significant in the Lipofundin® group ($P>0.05$). In the Lipoplus®/Lipidem® group, the postoperative infection incidence rate [3.1 % (1/32) compared to 9.4 % (3/32), $P=0.61$] and the SIRS incidence rate [6.3 % (2/32) compared to 15.6 % (5/32), $P=0.21$] were lower than in the Lipofundin® group. The APACHE II score was higher in the Lipoplus®/Lipidem® group but the difference was not statistically significant (3.6+/- 2.0 vs. 3.3+/- 2.1, $P=0.43$).

The length of hospital stay was significantly shorter in the Lipoplus®/Lipidem® group [6.4+/-1.1) d vs. (8.2+/-1.3) d, $P<0.03$].

Reduced hospital lenght of stay with Lipoplus®/Lipidem® (P=0.03)



CONCLUSION

Lipoplus®/Lipidem® fat emulsion can significantly improve the postoperative nutritional status and lower postoperative inflammatory response in patients with gastrointestinal malignancies.

Acknowledgement: Phase III study was conducted on behalf of B. Braun, Melsungen, Germany

Literature

Lipoplus® 200 mg/ml emulsion for infusion

COMPOSITION
1000 ml of emulsion contains:

Medium-chain triglycerides	100.0 g
Soya-bean oil, refined	80.0 g
Omega-3-acid triglycerides	20.0 g
Content of triglycerides	200 mg/ml (20 %)
Content of essential fatty acids	
Linoleic acid (omega-6)	38.4 - 46.4 g/l
Alpha-linolenic acid (omega-3)	4.0 - 8.8 g/l
Eicosapentaenoic acid and docosahexaenoic acid (omega-3)	8.6 - 17.2 g/l

Excipient with known effect:
1000 ml emulsion contains 2.6 mmol sodium (as sodium hydroxide and sodium oleate).

Excipients:
Egg phospholipids for injection, glycerol, sodium oleate, ascorbyl palmitate, all-rac-α-Tocopherol, sodium hydroxide (for pH adjustment), water for injections.

THERAPEUTIC INDICATIONS
Supply of energy, including a readily utilisable lipid component (medium-chain triglycerides) and essential omega-6 fatty acids and omega-3 fatty acids, as part of parenteral nutrition when oral or enteral nutrition is impossible, insufficient or contraindicated. Lipoplus® is indicated in adults, preterm and term neonates, infants and toddlers, children and adolescents.

CONTRAINDICATIONS
Hypersensitivity to the active substances, to egg, fish, peanut or soya protein or to any of the excipients. Severe hyperlipidaemia characterised by hypertriglyceridaemia (≥ 1000 mg/dl or 11.4 mmol/l); severe coagulopathy; intrahepatic cholestasis; severe hepatic insufficiency; severe renal insufficiency in absence of renal replacement therapy; acute thromboembolic events; fat embolism; acidosis. General contraindications to parenteral nutrition include unstable circulatory status with vital threat (states of collapse and shock); acute phases of cardiac infarction or stroke; unstable metabolic conditions (e.g. decompensated diabetes mellitus, severe sepsis, coma of unknown origin); inadequate cellular oxygen supply; disturbances of the electrolyte and fluid balance; acute pulmonary oedema; decompensated cardiac insufficiency.

UNDESIRABLE EFFECTS
The following listing includes a number of systemic adverse reactions that may be associated with the use of Lipoplus®. Under the conditions of correct use, in terms of dosing, monitoring, observation of safety restrictions and instructions, most of them are very rare (<1/10 000).

Undesirable effects are listed according to their frequencies as follows:

Rare:	(≥ 1/10000 to < 1/1000)
Very rare:	(< 1/10000)
Not known:	(cannot be estimated from the available data)

Blood and lymphatic system disorders
Very rare: Hypercoagulation
Not known: Leucopenia, thrombocytopenia

Immune system disorders
Very rare: Allergic reactions (e.g. anaphylactic reactions, dermal eruptions, laryngeal, oral and facial oedema)

Metabolism and nutrition disorders
Very rare: Hyperlipidaemia, metabolic acidosis. The frequency of these adverse reactions is dosedependent and may be higher under conditions of absolute or relative overdose
Very rare: Hyperglycaemia

Nervous system disorders
Very rare: Headache, drowsiness

Vascular disorders
Very rare: Hypertension or hypotension, flush

Respiratory, thoracic and mediastinal disorders
Very rare: Dyspnoea, cyanosis

Gastrointestinal disorders
Very rare: Nausea, vomiting, loss of appetite

Skin and subcutaneous tissue disorders
Very rare: Erythema, sweating

Hepatobiliary disorders
Not known: Cholestasis

Musculoskeletal and connective tissue disorders
Rare: Back, bones, chest and lumbar region pain

General disorders and administration site conditions
Very rare: Elevated body temperature, feeling cold, chills, fat overload syndrome (see below)

Should adverse reactions occur, the infusion must be stopped.

Should the triglyceride level rise to above 11.4 mmol/l (1000 mg/dl) during infusion, the infusion must be stopped. With levels above 4.6 mmol/l (400 mg/dl), the infusion may be continued at a reduced dosage. If the infusion is restarted, the patient should be carefully monitored, especially at the beginning, and serum triglycerides should be determined at short intervals.

Information on particular undesirable effects
Nausea, vomiting and lack of appetite are symptoms often related to conditions for which parenteral nutrition is indicated, and may be associated with parenteral nutrition at the same time.

Fat overload syndrome
Impaired capacity to eliminate triglycerides can lead to "fat overload syndrome" which may be caused by overdose. Possible signs of metabolic overload must be observed. The cause may be genetic (individually different metabolism) or the fat metabolism may be affected by ongoing or previous diseases. This syndrome may also appear during severe hypertriglyceridaemia, even at the recommended infusion rate, and in association with a sudden change in the patient's clinical condition, such as renal function impairment or infection. The fat overload syndrome is characterised by hyperlipidaemia, fever, fat infiltration, hepatomegaly with or without icterus, splenomegaly, anaemia, leucopenia, thrombocytopenia, coagulation disorder, haemolysis and reticulocytosis, abnormal liver function tests and coma. The symptoms are usually reversible if the infusion of the fat emulsion is discontinued. Should signs of a fat overload syndrome occur, the infusion of Lipoplus® must be discontinued immediately.

WARNINGS
Keep out of the sight and reach of children. For single use only. Any unused emulsion should be discarded.

MARKETING AUTHORIZATION HOLDER
B. Braun Melsungen AG, 34209 Melsungen, Germany

Last revision: 07/2020

Prescription only

Not all products are registered and approved for sale in all coutries or regions. Indications of use may also vary by country and region. Please contact your country representative for product availability and information.

Lipofundin® MCT/LCT*

COMPOSITION

1000 ml emulsion contain	Lipofundin® MCT/LCT 10%	Lipofundin® MCT/LCT 20%
Soybean oil	50.0 g	100.0 g
Mediumchain Triglycerides	50.0 g	100.0 g
Glycerol	25.0 g	25.0 g
Egg yolk phospholipids*	8.0 g	12.0 g
Sodium Oleate, α-Tocopherol*, Water for injections		
Caloric Value (kcal):	1022	1908
Theor. osmolarity (mOsmo/L):	345	380
pH:	6.5-8.8	6.5-8.5

* The amount of egg yolk phospholipids and α-tocopherol can vary is some countries. Please refer to the country representative. Soybean oil is a refined natural product containing neutral triglycerides of predominantly unsaturated fatty acids. Medium-chain triglycerides are a mixture of neutral triglycerides of mainly caprylic (about 60 %) and capric acid (about 40 %).

INDICATIONS
Lipofundin® MCT/LCT is indicated as a source of calories and essential fatty acids for patients requiring Parenteral Nutrition.

CONTRAINDICATIONS
The administration of Lipofundin® MCT/LCT is contraindicated in patients demonstrating disturbances in normal fat metabolism such as pathologic hyperlipaemia, lipoid nephrosis, or acute pancreatitis if accompanied by hyperlipaemia. It is further contraindicated in patients with ketoacidosis or hypoxia, in thromboembolism and in acute shock states.

PRECAUTIONS FOR USE
Caution should be exercised in administering intravenous fat emulsions in patients with metabolic acidosis, severe liver damage, pulmonary disease, sepsis, diseases of the reticuloendothelial system, anaemia or blood coagulation disorders or when there is danger of fat embolism. Administration of Lipofundin® MCT/LCT should be accompanied by simultaneous carbohydrate infusions making up to 40 % (at least) of the total calorie intake. When Lipofundin® MCT/LCT is administered, the patient's capacity to eliminate the infused fat from the circulation must be monitored. The lipaemia must clear between daily infusions. Especially where fat emulsions are administered for extended periods of time, the patient's haemogram, blood coagulation, liver function and platelet count should be closely monitored.Paediatric patients: studies have shown the safety and effectiveness of Lipofundin® MCT/LCT as part of total Parenteral Nutrition in neonates and older children.

Lipofundin® MCT/LCT has been aproved for usage in this patient population in some countries. Registration procedures are currently pursued in other countries. As long as approval has not been obtained in a specific country it is up to the judgement of the responsible physician whether or not to use Lipofundin® MCT/LCT in this patient group.

Use in pregnancy and lactation
The safety of Lipofundin® MCT/LCT during pregnancy and lactation has not been assessed, but its use during these periods is not considered to constitute a hazard. Nevertheless, medicines should not be used in pregnancy, especially during the first trimester, unless the expected benefit is thought to outweigh any possible risk to the foetus.

SPECIAL WARNINGS
The too rapid infusion of fat emulsions can cause fluid and/or fat overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, pulmonary oedema, impaired pulmonary diffusion capacity. A too rapid infusion of Lipofundin® MCT/LCT can also cause hyperketonaemia and/or metabolic acidosis, especially when carbohydrates are not administered simultaneously.

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Last revision: 01/2021

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Date of last revision: 03.2022