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A study on parenteral nutrition regimens in surgical and traumatological profile patients using all-in-one 3-compartment bag systems

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Abstact

Total Parenteral Nutrition (TPN) can be administered using individual containers or "all in one" type, commercial bags or multi bottle solutions prepared in the hospital drug-store. The aim of this work is to study the clinical efficiency and safety of surgical and traumatologic profile patients in Intensive Care Units (ICU) using all-in-one 3 compartment bag systems (TNA-peri). Fifteen adults with hypercatabolism syndrome of various genesis taking treatment in the surgical resuscitation department were included in this study and followed for four months (Nov 2013 to Feb 2014). In the course of study, depending upon the main pathology and performed surgical procedure, all the patients were divided into 2 groups. The first group patients (T-group) were given TNA-peri, 1 vial 2 times per day and the second group patients (K-group) were given standard multi-bottle systems containing amino acids solutions, glucose solutions, fat emulsions and micronutrients: vitamins, microelements, electrolytes in the volume estimated pursuant to the physiological needs. It is observed that the T-group receiving TNA-Peri, had more efficient recovery of hemoglobin and whole protein level with less duration of respiratory support, period of stay in ICU and frequency of suppurative septic complications compared to the K-group patients. This study shows that all-in-one, 3 component bags to be the system of choice to increase the clinical efficiency in surgical and traumatologic profile patients.

Keywords: Parenteral nutrition, TPN, intravenous, resuscitation and intensive care of traumatic patients, resuscitation and intensive care of surgical patients, clinical efficiency.

Introduction

Parenteral nutrition (PN) is an alternative or auxiliary approach applied in the cases when other methods to ensure adequate nutrition are not successful, provided that loss of possibility of nutrition by other methods is not obligatory or when such methods are either not possible or not safe. The main goal of PN is ensuring inflow of nutrient solution in the volume corresponding to the patient needs. The patients of intensive care units (ICU) need nutrition as long as hunger or insufficient feeding is associated with increase of complications and death rate. The surgical patients taking PN, the death rate was lower when compared with patients taking only glucose (Sandstrom et al. 1993). Delaying initiation of nutritional support exposes the surgical patients to energy deficits that cannot be compensated later on and sufficient energy has to be supplied using Enteral Nutrition or Parenteral Nutrition or combining both for enhanced recovery (Villet et al. 2005). Patients having contraindications to EF should be moved to PN within 24-48 hours (ESPEN 2009). Based on literature sources, PN is taken by 12% to 71%, and EF by 33% to 92% of patients in critical state and needing nutrition support (Payne-James et al. 1992; Hill et al. 1995; De Jonghe et al. 2001; Preiser et al. 1999; Lipman 1998; Heyland 2003).

The minimum volume of carbohydrate required to the patient composes 2g/kg of glucose per day (ESPEN 2009). There are no such convincing data confirming that carbohydrate is irreplaceable nutrient for a human being as there are for certain amino acids, fatty acids and micronutirents (Westman 2002). Ability for endogenous synthesis of higher volume of glucose (gluconeogenesis) from lactate, glycerin as well as in kidneys (Joseph et al. 2000) and, probably, in other tissues such as muscular tissue and bowels, looks like to be sufficient for ensuring complete autonomy. Nevertheless, glucose is a convenient and safe source of energy for use in PN.

Hyperglycemia (glucose level >10mmol/l) may cause death of a patient in a critical state. Such cases should be prevented in order to reduce the risk of complication in critical care settings (ESPEN 2009). Use of lipids (0.7g/kg/day to 1.5g/kg/day) allows reducing the volume of carbohydrates and making the control over glucose level easier (ESPEN 2009; Waitzberg et al. 2006). Fat emulsion used in parenteral nutrition consists of triclyceride and phospholipids acting as emulsifier. Applications of fat emulsions are associated with high rate of complications in surgical profile patients and patients in critical state (Calder 2006). If the patient is prescribed with

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PN, balanced solution of amino acids should be introduced with the speed ensuring arrival of amino acids in the volume of 1.3-1.5g/kg of perfect body weight per day, combined with adequate volume of energy substrate (ESPEN 2009). Many microelements and vitamins are also required for antioxidant protection. PN solutions represented in the market containing only amino acids, glucose, lipids and a number of electrolytes and having no microelements and vitamins. The microelements and vitamins require special subscription based on the surgical or critical care patient needs.

Use of individual containers for PN requires many manipulations with infusion system and catheter which is associated with higher risk of mistakes during solution introduction as well as with infectious and metabolic complications (Durand-Zaleski et al. 1997). The all-in-one type containers were cost effective when compared with multi bottle individual container systems (Pichard et al. 2000).

Commercial production of 3-compartment bags of "all in one" parenteral nutrition system was preceded by PN solutions mixed in one plastic bag in the hospital drug-store. However, such bags require experienced and well-trained people, specially equipped room and adhering of strict aseptic conditions which limits the application of the method in clinical practice. Using advanced scientific techniques, scientists have developed 2 or 3-compartment plastic bags containing solutions of amino acids, glucose and fat emulsions in various combinations including and excluding electrolyte. The goal of this work is to study the clinical efficiency and safety of surgical and traumatologic profile patients in Intensive Care Units (ICU).

MATERIAL AND METHODS

Fifteen adults with hypercatabolism syndrome of various genesis taking treatment in the Surgical Resuscitation Department, Tashkent Medical Academy, Ministry of Health of the Republic of Uzbekistan, Uzbekistan for the period from November 2013 to February 2014. The type of surgical procedure, complications, hypertension and sex were shown in Table 1.

Table 1: *Patients Clinical and Demographic Characteristics*

Characteristics	TNA-Peri Group (T) (n=7) (19-60 years)	Control Group (K) (n=8) (23 - 48 years)	P
Female	3	4	0.03
Male	4	4	
Type of surgical procedure			
Orthopedic	1	-	0.025
Abdominal	2	4	
Chest	2	1	0.078
Cerebral	3	4	
Urological	3	3	0.048
Traumatologic	4	4	
Complication nature			
Peritonitis	4	4	0.04
Sepsis	1	2	
Pneumonia	1	1	0.054
Urinary infection	1	1	
Hypotension	5	4	0.03

*****reliability of differences of indicators under study compared to initial values

The patients were divided into two groups depending on the main pathology, surgical procedure and selection of nutrition type. The multi-component medicine, TNA-Peri (Claris Lifesciences, India) (Appendix 1) is composed of three macronutrients placed in three compartment Bag container containing soyabean oil (20% lipid emulsion), amino Acid (10% solution of amino acids with electrolytes) and dextrose (15%).

The components are divided into three different partitions in order to prevent chemical reaction between the ingredients. The partitions can be destroyed manually by twisting of bag. After mixing all ingredients, the micronutrients (vitamins, microelements and electrolytes) can be added through a special port in aseptic environment. TNA-Peri may be stored 18 months at room temperature. The total volume of the bag after mixing is 2000ml.

The first group (T-group), containing seven patients, was prescribed with PN treatment with TNA-Peri on the second day, 1 vial 2 times per day.

The second group (K-group) with 8 control patients was given PN by one-component medicines containing amino acids solutions, glucose solutions, fat emulsions and micronutrients: vitamins, microelements, electrolytes in the volume estimated pursuant to the physiological needs.

Our clinic takes these drugs for PN in accordance with the requirements of ICU. Amino acid and fat emulsions our clinic buys from manufacturers. Most often these medications are Infezol (Berlin-Chemie AG/ Menarini Group, Germany) (370 kcal / l), Nirpid (Nirma Limited (Healthcare Division), India). Glucose solutions (5%, 10%, 20%, 40%), electrolyte solutions (potassium chloride, magnesium sulfate) and vitamins (ascorbic acid) are produced in the clinic pharmacy.

These drugs for PN administered to the patient group K for continuous infusion over days.
The main difference in the treatment of patients in group K was that they receive the drugs were single component. In addition, they were administered simultaneously or sequentially (one after another) rather than in a single container. In addition to the above, for the correction of hemoglobin level and plasma protein group K patients needed blood and plasma transfusion.

The daily caloric needs was calculated the same for both groups, and was at least 25-30 kcal / kg. However, for the patients of group K for achievement of necessary level of calories it was necessary to injection of great volume of solutions, considering their low energetic value. For example: 40% Glucose – 1600 ml, Infesol 40 – 1600 ml, Nirpid 20 – 1200 ml (per day).

Details of the groups were tabulated (Table 1). About 50% of the patients had volemic, electrolyte and metabolic disorder, serious anemia. Starting from 5-6 days, the patients were treated with mixed feeding before moving to complete EF.

The patients had no convincing differences in gravity of condition expressed as per APACHE II scale (acute physiology and chronic health evaluation – 21,2±2,5 points). Indicators such as proteins, energy metabolism, and metabolic status in early post operative period (2-5 days after surgical procedure or trauma) were monitored for 6 days for the T-group. These indicators were analyzed statistically using Excel 5.0 (Microsoft, USA) software package. The reliability of differences between values of indicators were evaluated using T-criteria Student when < 0.01 (Table 2 and 3).

Results and Discussion

Table 2: *Dynamic of laboratory blood tests of T Group patients (n=7) (M±σ)*

Indicators	Day				
	2nd	3rd	4th	5th	6th
Hb	91.0±3.2	105.1±2.3*	114.2±3.6*	116.6±3.6*	124.1±4.2*
Ht, %	27.2±2.4	32.2±2.6*	33.8±3.4*	34.4±2.8*	36.1±2.6*
Glucose, mmol/l	8.2±0.2	8.6±0.4	6.5±1.4*	5.1±1.1*	5.4±0.6*
Whole protein	45.5±1.4	50.7±1.3*	51.3±1.3	56.5±2.3*	66.4±2.2*
Urea, mmol/l	7.1±0.4	5.0±0.6*	2.4±0.3*	4.5±0.6*	4.8±1.4*
Creatinine, mcmol/l	85.2±4.1	75.0±5.2*	70.0±4.2*	45.5±3.6*	33.8±5.6
K^+, mmol/l	3.6±0.6	3.6±0.2	3.8±1.1	3.6±1.3	4.3±0.6
Na^+, mmol/l	135.4±2.1	136.6±2.1	131.8±1.7	131.5±1.3	138.7±1.8
Amylase, unit/l	56.1±4.4	81.3±3.6*	100.6±6.8	112.2±7.6*	103.4±7.6*
pH	7.33±0.21	7.38±0.43	7.40±0.34*	7.42±0.31*	7.40±0.34*

*****reliability of differences of indicators under study compared to initial values ($P < 0.01$)

Table 3: *Dynamic of laboratory blood tests of K Group patients (n=8) (M±σ)*

Indicators	Day				
	2nd	3rd	4th	5th	6th
Hb	91.0±3.2	89.0±1.4*	94.3±2.8*	96.6±2.2*	102.1±2.2*
Ht, %	27.2±2.4	26.1±1.8*	30.1±3.3*	34.8±2.6*	38.5±2.4*
Glucose, mmol/l	8.2±0.2	10.6±1.4	15.5±1.8*	13.1±2.1*	14.1±2.6*
Whole protein	45.5±1.4	49.2±2.3*	52.4±1.6	55.4±1.3*	59.5±2.4*
Urea, mmol/l	7.1±0.4	6.8±0.8*	6.4±0.4*	5.4±1.1*	5.8±1.0*
Creatinine, mcmol/l	85.2±4.1	78.1±4.2*	74.0±3.3*	66.0±4.6*	62.1±2.6
K^+, mmol/l	3.6±0.6	3.5±0.1	3.5±0.1	4.5±0.3	4.2±0.3
Na^+, mmol/l	135.4±2.1	138.2±1.1	132.2±1.3	141.1±0.3	138.8±0.8
Amylase, unit/l	80.1±3.4	85.4±3.0	92.0±4.2	94.0±5.8	90.8±5.5
pH	7.33±0.21	7.30±0.24	7.32±0.28*	7.33±1.1*	7.35±0.48*

***** - reliability of differences of indicators under study compared to initial values ($P < 0.01$)

Despite the serious condition of the patients, in the course of research, we have observed increase in blood plasma level, whole protein, hemoglobin, hematocrit compared to the initial values. After 3 to 4 days, we noted normalization of blood pH and reduction of creatinine. After 5 to 6 days, transient increase in blood amylase and reduction of creatinine level was observed. However, in the group K the normalization of hemoglobin level, hematocrit, whole protein, urea, creatinine and pH is much slower than in group T. The first group with TNA-Peri, has not shown symptoms of hyperglycemia, when compared with K-Group. It is also found that the K-group patients require insulin. Specific changes in the level of sodium and potassium plasma, there was not a group K, or the group T. Further parameters like average duration of respiratory support, hemodynamic instability (hypotension), stay in ICU and hospital, need for plasma and blood transfusion, frequency of septic complications (nosocomial pneumonia, sepsis), mortality were tabulated (Table 4). These parameters were the basic vital parameters defining an outcome of disease and a condition of an organism of the patient.

Table 4: Impact of medicaments for PN to system physiological characteristics

Characteristics	TNA-Peri Group (T) (n=7) (19-60 years)	Control Group (K) (n=8) (23-48 years)	P
Average duration of respiratory support, days	5.1±0.4	9.3±0.9	0.0001
Average duration of hemodynamic instability (hypotension), days	3.8±0.4	8.8±1.1	0.004
Average duration of stay in ICU, days	7.4±1.1	15.4±1.4	0.03
Average length of hospital stay, days	11.6±2.2	27.7±3.8	0.04
Need for plasma and blood transfusion, number of patients (%)	0	6 (75%)	0.027
Frequency of suppurative septic complications, %	7.1±0.9	27.3±1.3	0.0002
Mortality, %	14.3±0.6	18.2±1.2	0.0001

*****reliability of differences of indicators under study compared to initial values

Conclusion

Results from our study clearly states that the T-Group patients receiving TNA-Peri showed recovery of hemoglobin, stabilization of whole protein level and improvement of nitrogen balance, in less duration when compared with K group patients. It is also found that the average duration of respiratory support, average duration of stay in ICU, frequency of suppurative septic complications, and mortality were observed to be less for T Group patients resulting in reduction of treatment cost and medical personnel working hours. Thus, nutrients introduction through all-in-one, 3 compartment bags (TNA-peri) has positive impact at metabolic and adaptation processes of the patients in critical state, within the short period of time normalizing metabolism of protein, fats and carbohydrates, thus ensuring earlier transfer of catabolic phase of metabolism to anabolic one. TNA-Peri, medicine was proved to be successful and can be used in ICU for various surgical and traumatologic profile patients. Application of multi compartment bags can result in optimal solution for ensuring nutrition status of adults in the hospital and enhanced recovery after surgery.

Reference

Calder PC. n-3 polyunsaturated fatty acids, inflammation, and inflammatory diseases. Am J Clin Nutr 2006;83:1505S–19S.

De Jonghe BC, Appere-De Vecchi, et al. A prospective survey of nutritional support practices in intensive care units patients: what is prescribed? what is delivered? Crit Care Med 2001;29:8–12.

Durand-Zaleski I, Delaunay L, Langeron O, Belda E, Astier A, Brun-Bruisson C. Infection risk and cost-effectiveness of

commercial bags or glass bottles for total parenteral nutrition. Infect Control Hosp Epidemiol 1997;18:183–8.

ESPEN Guidelines. Clin Nutr 2009; 28:359-479.

Heyland DK, Schroter-Noppe D, Drover JW, et al. Nutrition support in the critical care setting: current practice in Canadian ICUs – opportunities for improvement? J Parenter Enteral Nutr 2003;27:74–83.

Hill SA, Nielsen MS, Lennard-Jones JE. Nutrition support in intensive care units in England and Wales: a survey. Eur J Clin Nutr 1995;49:371–8.

Joseph SE, Heaton N, Potter D, Pernet A, Umpleby MA, Amiel SA. Renal glucose production compensates for the liver during the anhepatic phase of liver transplantation. Diabetes 2000;49:450–6.

Lipman TO. Grains or veins: is enteral nutrition really better than parenteral nutrition? A look at the evidence. J Parenter Enteral Nutr 1998;22:167–82.

Preiser JC, Berre. J, Carpentier Y, et al. Management of nutrition in European intensive careunits: results ofaquestionnaire. Intensive CareMed 1999;25:95–101.

Pichard C, Schwarz G, Frei A, et al. Economic investigation of the use of three compartment total parenteral nutrition bag: a prospective randomized unblinded controlled study. Clin Nutr 2000;19:245–51.

Payne-James JJ, de Gara CJ, Grimble GK, et al. Artificial nutrition support in hospitals in the United Kingdom – 1991: second national survey. Clin Nutr 1992;11:187–92.

Sandstrom R, Drott C, Hyltander A, et al. The effect of postoperative intravenous feeding (TPN) on outcome following major surgery evaluated in a randomized study. Ann Surg 1993;217:185–95.

Villet S, Chiolero RL, Bollmann MD, et al. Negative impact of hypocaloric feeding and energy balance on clinical outcome in ICU patients. Clin Nutr 2005;24:502–9.

Waitzberg DL, Torrinhas RS, Jacintho TM. New parenteral lipid emulsions for clinical use. J Parenter Enteral Nutr 2006;30:351–67.

Westman EC. Is dietary carbohydrate essential for human nutrition? Am J Clin Nutr 2002;75:951–3.

Appendix - 1

Compartment 1 - 1060 ml

Glucose Intravenous Infusion BP (150 g/L)

Each 100 ml contains :

Anhydrous Glucose BP	15.00 g
Water for Injections BP	q. s.

Compartment 3 - 340 ml

Intravenous Fat Emulsion with Medium & Long Chain Triglycerides (20% w/v) **(CELEPID™ MCT - LCT 20%)**

Each 100 ml (of emulsion) contains:

Soybean Oil USP	10.00 g
Medium Chain Triglycerides BP	10.00 g
Egg Lecithin	1.20 g
Glycerol USP	2.50 g
Water for Injections BP	q. s.

Storage: Store below 25°C. Store in over wrap. Do not freeze.

Use only when the solutions are clear, homogenous & practically free from particles, and container is undamaged. Do not use if separation of the emulsion is observed. Discard any unused mixture. Keep out of reach of children.

Do not connect in series. Do not administer before or after administration of blood through the same infusion equipment. Do not exceed the recommended infusion rate.

Open both the seals and mix well according to instructions for use.

For dosage, administration, see package insert.

Additives may be incompatible. Consult the manufacturer for further details.

Compartment 2 - 600 ml

Aminoacids (10% w/v) Injection with Electrolytes **(CELEMIN™-10 PLUS)**

Each 100 ml contains:

L – Isoleucine USP	0.510 g
L – Leucine USP	0.890 g
L - Lysine Hydrochloride USP	0.700 g
L – Methionine USP	0.380 g
L – Phenylalanine USP	0.510 g
L – Threonine USP	0.410 g
L – Tryptophan USP	0.180 g
L – Valine USP	0.480 g
L – Arginine USP	0.920 g
L – Histidine USP	0.520 g
Glycine USP	0.790 g
L – Alanine USP	1.370 g
L – Proline USP	0.890 g
L - Aspartic Acid BP	0.130 g
L - Asparagine H_2O	0.372 g
L - Cysteine Hydrochloride H_2O USP	0.073 g
L - Glutamic Acid BP	0.460 g
L - Ornithine Hydrochloride	0.320 g
L – Serine USP	0.240 g
L – Tyrosine USP	0.030 g
Acetyltyrosine BP	0.123 g
L - Malic Acid	0.100 g
Sodium Acetate $3H_2O$ BP	0.395 g
Potassium Acetate USP	0.245 g
Magnesium Acetate $4H_2O$ BP	0.056 g
Sodium Dihydrogen Phosphate $2H_2O$ BP	0.140 g
Water for Injections BP	q. s.

After mixing, TNA™ - *Peri* will provide

Total Volume	:	**2000 ml**
Total Energy (kcal)	:	**1525**
Non protein Energy (kcal)	:	**1285**
Nitrogen (g)	:	**9.6**
Amino Acids (g)	:	**60**
Dextrose (g)	:	**159**
Lipids (g)	:	**68**
Na^+ (mmol)	:	27.00
K^+ (mmol)	:	15.00
Mg^{+2} (mmol)	:	1.50
Acetate$^-$ (mmol)	:	35.40
Cl^- (mmol)	:	37.20
$H_2PO_4^-$ (mmol)	:	5.40
L-Malate^{-2}(mmol)	:	4.50
Osmolarity (mOsmol/L)	:	**818**
pH	:	5.95

For I.V. use only.