Comparison of a Immunonutrition Formula Enriched Arginine, Glutamine and Omega-3 Fatty Acid†, with a Currently High-Enriched Enteral Nutrition†† for Trauma Patients

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Abstract

The severe trauma or burn patients required aggressive resuscitation, operation and metabolic support to reduce morbidity and motality. Nutrition is one of the most important treatment for these patients, improving body protein and immune function, reducing rate of infection and shortening hospitalization.

Method : To evaluate the metabolic and immune effects of dietary arginine, glutamine and omega-3 fatty acids (fish oil) supplementation, we performed a prospective study in patients age 15-60 yrs after severe trauma (Injury Severity Scores (ISS) 15-30) or burn patients (body surface area (BSA) 30-60%) in Siriraj Hospital. They were randomized to receive either Neomune or Traumacal. The nasogastric feeding was started in post-injury day 2 (PID2) with half of concentration at the rate of 30 ml/h. From PID3 to PID10, the normal concentration was administered at the rate of 80-100 ml/h depending on optimal caloric requirement. All patients received 5 per cent dextrose in half or full strength saline solution as clinically indicated. No other oral nutrients apart from study formula were allowed during the study. Blood sample was with-drawn on PID2, PID6 and PID11 for measurements of CBC, coagulogram, albumin, transferrin, CRP, LFT, BUN, Cr, CD_3, CD_{19}, CD_4, CD_8, C_3, IgG, IgM, and IgA. Nitrogen balance was calculated from UUN. Unpaired student *t*-test was applied to compare variables between the two groups.

Results : 36 patients were selected (16 trauma and 20 burn), male = 29, mean age = 29.86 yrs. The patients were divided equally into two groups to receive Neomune or Traumacal. The data were compared and showed significance on total protein on PID11 (Neomune = 6.52 ± 1.29, Traumacal = 5.59 ± 1.21, $p = 0.03$) and serum triglycerides on PID11 (Neomune = 128.39 ± 53.45, Traumacal = 186.25 ± 84.07, $p = 0.02$). The ICU stay was observed shorter in Neomune than in Traumacal group (3.41 and 7.83 days) with no statistical significance. The wean-off respirator day was also shorter in Neomune than in Traumacal group (2.71 and 7.39 days). One patient in each group died.

Conclusions : The feeding of Neomune in critically injured patients was well tolerated as Traumacal and significant improvement was observed in serum protein. Shorten ICU stay and wean- off respirator day may benefit from using the immunonutrient formula.

Key word : Immunonutrition, Arginine, Glutamine Omega-3 Fatty Acid, Trauma, Burn

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† Neomune®

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Patients with severe trauma are in the some immunocompromised state as patients with cancer or post-operative patients(1). According to the severe stress state, inadequate nutrients intake during treatment promotes protein catabolism and organ dysfunction(2). Some studies found some nutrients improved immunity in post-injury patients. Those nutrients include Arginine(3), Glutamine(4) and Omega-3 fatty acid(5) which have a direct effect on T lymphocytes and macrophage(6-8). Thus, tube feedings should have these nutrients added to complete the formula. This study focused on the comparison of Neomune®, immunonutrition formula enriched Arginine, Glutamine and Omega-3 fatty acid, with Traumacal®, currently high-enriched enteral nutrition for trauma patients.

MATERIAL AND METHOD

This prospective and randomized study in Siriraj Hospital was approved by the Committee of Human Rights of the Faculty of Medicine, Siriraj Hospital. General trauma and burn patients aged 15-60 years with Injury Severity Scores (ISS) between 15-30 and burns over 30-60 per cent burn of the body surface area (BSA) were randomized. These patients were expected to have enteral feeding for at least 9 days. The exclusion criteria were patients with diabetes mellitus, liver disease (hepatic dysfunction, serum bilirubin > 3.0 mg/dl), renal disease (serum creatinine > 2.5 mg/dl), infection and steroids treatment both in pre and post study. The subjects weighed not more than 130 per cent of their ideal body weight. Informed written consent was obtained from the patients or the patients' relatives.

Randomized patients were divided into 2 groups: The control group with Traumacal®, Group A, and study group with Neomune®, Group B. The study was started on the 2nd day after injury (post-injury day 2 = PID2) after the patients had already been well resuscitated and operated on, and continuous feeding through an NG tube with half strength 30 ml/h of formula. On the PID3 through PID11 the concentration and volume of formula was increased to the requirement of the patients (calculated by Harris-Benedict Equation). The rate of feeding was about 80-100 ml/h. Patients did not receive oral intake during the 9 days of the study period. 5 per cent Dextrose solution was supplemented as needed.

The value of CBC, coagulogram, albumin, transferrin, CRP, LFT, BUN, Cr, CD_3, CD_{19}, CD_4, CD_8, C_3, IgG, IgM, IgA and aminogram were compared on PID2, PID6 and PID11. The urine urea nitrogen in 24 hours urine was measured to calculate Nitrogen Balance (NB). Moreover, complications,

hospitalization, ICU day and wean-off respirator day were compared in both groups of patients by Student T Test at $p < 0.05$.

The composition of formula is shown in Table 1.

RESULT

The characteristics of patients are shown in Table 2.

Most of the patients tolerated the tube feeding quite well. Gastrointestinal complications such as flatulence, dyspepsia and diarrhea were rare. This indicated that Neomune® could be used as well as other enteral feeding without severe complications.

The results showed 28.78 ± 25.74 days of hospitalization in the Traumacal® group and 44.95 ± 30.27 days in the Neomune® group, 7.83 ± 13.60 days of ICU day in the Traumacal® group and 3.41 ± 5.81 days in the Neomune® group, 7.39 ± 13.54 days of wean-off respirator days in the Traumacal® group and 2.71 ± 5.21 days in the Neomune® group. There was no statistical difference in the results. The conclusion is illustrated in Fig. 1.

The consequence of amino acids showed insignificant improvement of Glutamine in both groups of subjects. However, the level of Arginine and Ornitine was significantly higher in the Neomune® group on PID11.

Biochemistry results were not much different for both groups of patients as shown in Table 3.

Immunological results were not significantly different as shown in Table 4.

DISCUSSION

Malnutrition and surgery have an effect on cellular and humoral immunity[9]. It is believed that inflammation gives the direct action on the immunity *via* the function of macrophage and the response of lymphocyte proliferation. Nowadays, studies have concentrated on nutrients to stimulate the function

Table 1. Composition of formula.

Formula	Traumacal®	Neomune®
Classification	High stressed, lactose-free hypercaloric, high nitrogen	Immuno-enriched, lactose-free normal caloric, high nitrogen
Protein (g/L)	83	62.5
Fat (g/L)	68	28
Carbohydrate (g/L)	143	125
NPC : N	90 : 1	75 : 1
Osmolarity (mOsm/L)	490	330
Protein source (%)	Casein 100%	Casein 70% Arginine 20% Glutamine 10%
Fat source (%)	Soy oil 70% MCT 30%	Corn oil 30% MCT 50% Fish oil 20%

Table 2. The characteristics of patients.

	Traumacal® (A)	Neomune® (B)	P-value
No. of cases	18	18	
Male : Female	16 : 2	13 : 5	
Trauma : Burn (cases)	9 : 9	7 : 11	
Average ISS	24.5	24.83	NS
Average % burn	43.5 ± 10	44.18 ± 12	NS
Average Age	30.89 ± 13.24	28.83 ± 12.47	NS
Initial albumin (g/dl)	2.87 ± 0.63	2.81 ± 0.57	NS
Initial transferrin (g/L)	1.27 ± 0.35	1.43 ± 0.9	NS
Body weight (kg)	63.66 ± 8.81	61.04 ± 8.32	NS

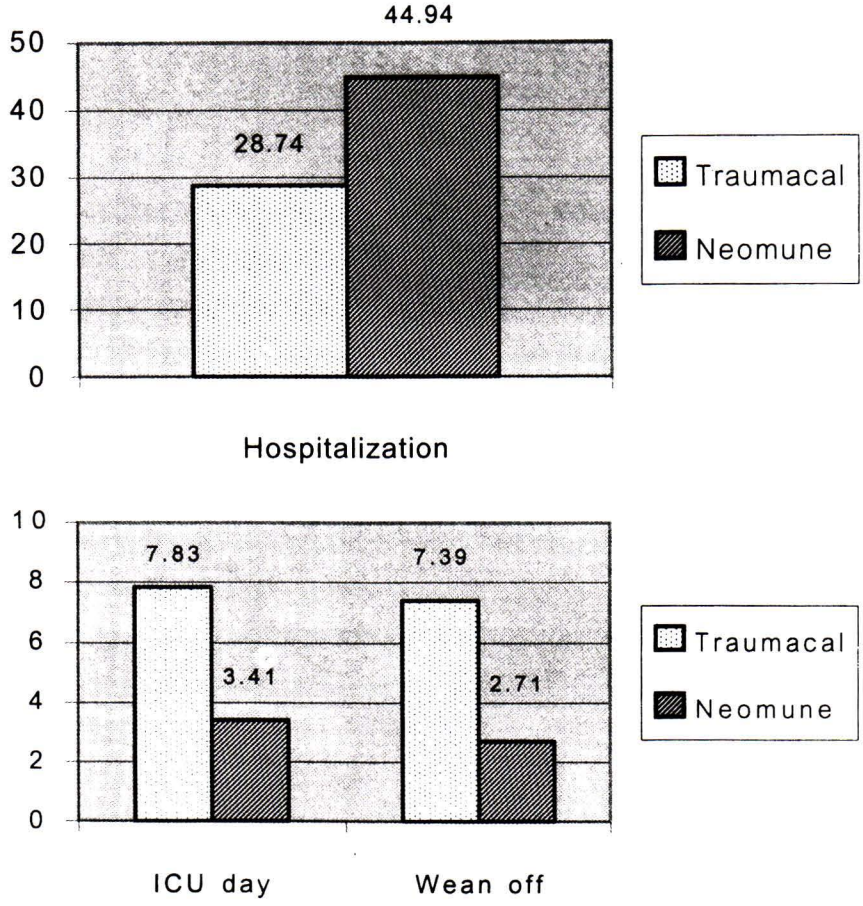

Fig. 1. Hospitalization, ICU days and wean-off respirator days.

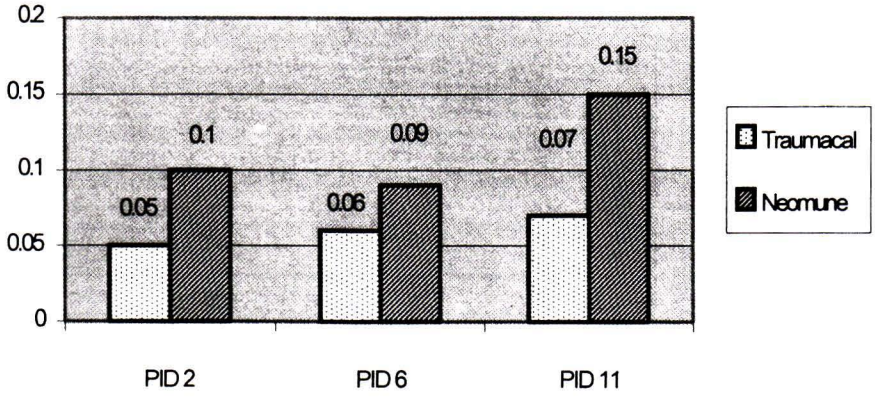

Fig. 2. The amount of Glutamine.

Table 3. Biochemistry values.

	PID2		PID6		PID11		P-value
	Traumacal	Neomune	Traumacal	Neomune	Traumacal	Neomune	
Total prot	4.87 ± 0.77	4.58 ± 1.16	5.57 ± 0.97	5.51 ± 1.0	5.59 ± 1.21	6.52 ± 1.29*	*0.03
Albumin	2.87 ± 0.63	2.81 ± 0.57	3.11 ± 0.81	3.06 ± 0.78	2.84 ± 0.9	3.21 ± 0.94	NS
Transferrin	1.27 ± 0.35	1.43 ± 0.9	1.39 ± 0.45	1.21 ± 0.45	1.59 ± 0.65	1.37 ± 0.4	NS
T Bilirubin	0.95 ± 0.51	0.88 ± 0.61	0.88 ± 0.7	1.34 ± 2.01	0.6 ± 0.88	0.96 ± 1.27	NS
SGOT	208.5 ± 248.79	103.5 ± 94.07	90.89 ± 35.79	88.17 ± 67.62	98.38 ± 105.13	94.61 ± 56.97	NS
SGPT	143.78 ± 171.02	74.0 ± 57.15	81.44 ± 36.85	80.5 ± 60.28	91.69 ± 64.45	100.44 ± 69.05	NS
Alkal Phos	54.89 ± 16.05	59.06 ± 23.34	131.53 ± 68.63	176.83 ± 146.74	174.19 ± 83.53	213.11 ± 119.42	NS
Cholesterol	113.81 ± 121.41	115.28 ± 26.4	106.53 ± 29.13	102.17 ± 35.53	110.33 ± 38.41	103.06 ± 40.18	NS
Triglyceride	125.76 ± 52.68	118.59 ± 50.61	148.61 ± 82	112.28 ± 43.43	186.25 ± 84.07	128.39 ± 53.45*	0.02
HDLC	33.0 ± 10.34	27.2 ± 10.78	24.36 ± 16.81	21.31 ± 7.28	23.0 ± 2.86	18.33 ± 7.24	NS
BUN	11.39 ± 4.03	12.67 ± 9.92	17.06 ± 3.44	17.39 ± 4.51	25.63 ± 16.04	21.56 ± 8.4	NS
Creatinine	0.9 ± 0.22	0.91 ± 0.45	0.76 ± 0.14	0.78 ± 0.15	0.98 ± 0.93	0.77 ± 0.21	NS
Glucose	150.22 ± 40.84	143.71 ± 30.5	155.22 ± 70.81	147.61 ± 38.23	170.56 ± 156.66	131.59 ± 25.95	NS
Calcium	7.59 ± 0.72	7.57 ± 0.86	7.81 ± 0.77	7.64 ± 0.86	7.91 ± 0.99	8.32 ± 1.31	NS
Magnesium	1.64 ± 0.29	1.67 ± 0.31	1.99 ± 0.28	2.15 ± 0.55	2.18 ± 0.41	2.29 ± 0.66	NS
Phosphate	2.7 ± 0.68	2.47 ± 0.67	2.87 ± 1.27	3.13 ± 1.37	4.21 ± 1.36	4.26 ± 1.53	NS
Sodium	135.22 ± 6.11	132.78 ± 5.47	134.44 ± 4.09	133.33 ± 4.84	133.69 ± 7.69	133.83 ± 4.67	NS
CRP	201.08 ± 142.97	192.97 ± 128.83	183.53 ± 114.64	163.78 ± 93.6	90.6 ± 68.26	113.93 ± 65.53	NS

* = $p < 0.05$

of cellular immunity which affect macrophage and lymphocyte. These nutrients include arginine, glutamine and omega-3 fatty acid called immunonutrition[10].

Reynolds[11] found arginine activated T cell proliferation after stimulation by mitogen and cytokines. Additionally, arginine improved lymphocyte blastogenesis[12] in post-operative patients. Which study showed Neomune® increased the level of Arginine more than Traumacal®.

Glutamine[13], a conditional-essential amino acid, plays a crucial role in enterocytes. This nutrient improves cellular activity and protects bacterial permeability. The decline level of glutamine in a critically ill state means more consumption of glutamine by enterocytes. Adding 0.1-0.57 g/kg/day of glutamine in tube feeding or parenteral nutrition has no disadvantage[14]. From the present study, the amount of glutamine was not significantly increased which may be due to timing of sample collection causing the glutamine to be degraded. Furthermore, the level of glutamine could not be directly measured in the cell. Thus, the value was inaccurate[15].

Omega-3 fatty acid directly affects the function of monocyte by membrane characteristic alteration, prostaglandin E2 synthesis that has the action of macrophage phagocytosis, IL-1 and superoxide synthesis. Moreover, omega-3 fatty acid reduces cellular immune response reaction by compete arachidonic acid resulting in less inflammation. The ratio of omega-6 fatty acid by omega-3 fatty acid was 5 : 1. Nevertheless, this was not confirmed.

Also, medium chain triglycerides (MCT)[16] diminishes the amount of arachinodic acid. There are studies which clearly support that the mixture of MCT and long chain triglycerides (LCT) can protect the problem of immunosuppression[17,18]. So, proper composition[19] of Neomune® with MCT, omega-3 and essential fatty acid benefits anti-inflammatory patients and decreases immune disorder.

To date, a lot of studies in immunonutrition have shown the result of immunoenhancing and improved treatment[20-23]. The subjects of the present comparative study were similar in severity of disease, age and weight. The compared nutrients were Traumacal®, currently used in severe trauma patients. Traumacal® contains higher protein and energy than Neomune®; however, the amount of nutrients was adjusted to the requirement of each patient.

Table 4. Immunological results.

	PID2		PID6		PID11		P-value
	Traumacal	Neomune	Traumacal	Neomune	Traumacal	Neomune	
CD3	951.41 ± 824.91	862.82 ± 570.08	1,542.21 ± 1,011.18	1,759.41 ± 1,333.24	2,076.0 ± 1,653.91	1,327.44 ± 846.93	NS
CD4	526.65 ± 511.10	821.71 ± 1,627.67	691.57 ± 516.9	989.59 ± 824.5	1,028.71 ± 679.54	756.0 ± 6,000.0	NS
CD8	385.0 ± 313.21	373.06 ± 268.98	669.86 ± 734.32	666.29 ± 476.82	703.88 ± 398.07	516.19 ± 285.08	NS
CD19	365.65 ± 228.83	373.65 ± 292.6	668.71 ± 794.63	606.94 ± 539.7	573.88 ± 429.23	372.06 ± 248.14	NS
CD4 : CD8	1.31 ± 0.53	1.42 ± 0.48	1.43 ± 0.74 1	59 ± 0.65	1.62 ± 0.92	1.6 ± 0.85	NS
C3	0.62 ± 0.23	0.96 ± 0.37	1.21 ± 0.79	1.33 ± 0.52	1.24 ± 0.5	1.33 ± 0.29	NS
IgG	9.88 ± 2.47	11.43 ± 6.36	10.43 ± 3.33	13.08 ± 4.93	15.6 ± 5.22	14.36 ± 5.88	NS
IgM	1.23 ± 1.99	0.91 ± 0.34	1.41 ± 1.5	1.09 ± 0.67	1.17 ± 0.94	1.16 ± 0.51	NS
IgA	2.18 ± 0.87	1.87 ± 0.72	2.27 ± 0.69	2.6 ± 1.03	3.22 ± 1.42	2.86 ± 1.41	NS

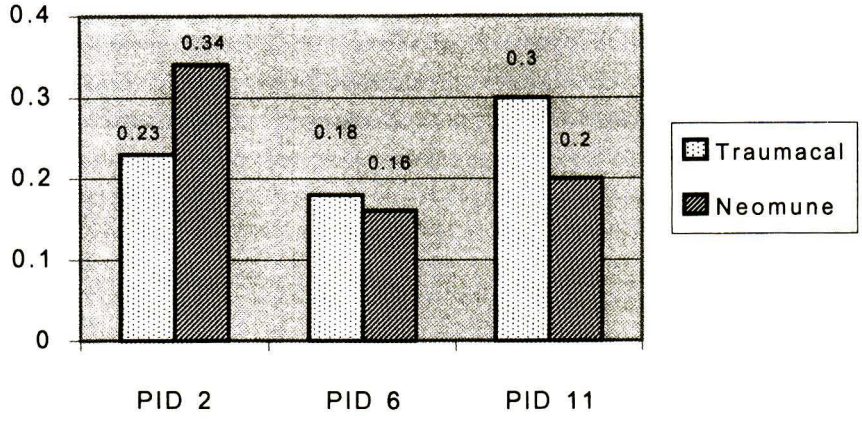

Fig. 3. The amount of Arginine (p-value = 0.02 in PID11).

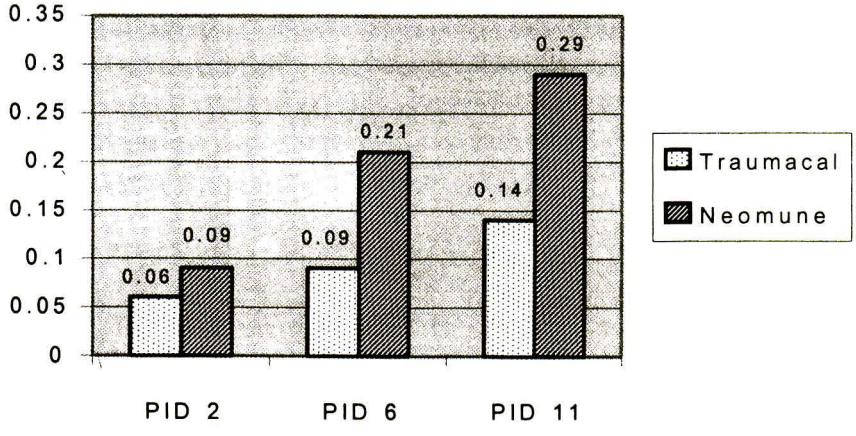

Fig. 4. The amount of Ornitine (p-value = 0.03 in PID2, 0.02 in PID6).

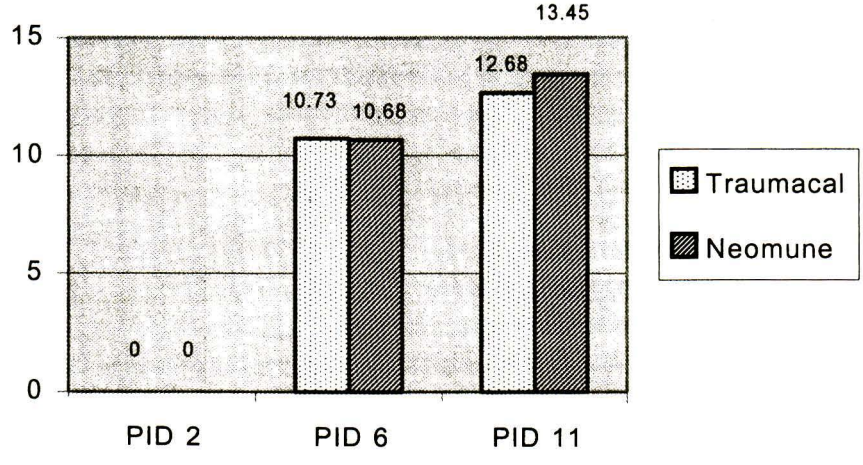

Fig. 5. The difference of Nitrogen balance.

Clinical outcome in both groups of patients were different. Group B (Neomune®) had longer hospitalization than group A. Besides, this outcome could not be considered as depending on several factors; no relatives to respond to patients or the problem of self care, problems which a lot of burn patients have. Data of ICU day and wean-off respiratory day should be used. Neomune® gave a good result in patient recovering except it was not statistically significant.

Total protein in the Neomune® group was significantly higher; though, the amount of protein in Traumacal® was more than Neomune®. This showed protein utilization in Neomune® was better than in Traumacal®. Nitrogen balance at the beginning of both groups were negative. On the 9th day of nutrition support, nitrogen balance turned to positive, and the difference of nitrogen balance from the beginning of Neomune® was greater than of Traumacal®. Briefly, Neomune® yielded protein utilization. In theory, trauma and infection cause a lot of nitrogen loss. Nutrition support alone cannot improve nitrogen. Infection protection, growth hormone or IGF-1 treatment can improve retention of nitrogen; which takes weeks to resolve.

Biochemistry results in the present study indicated no difference in kidney or liver function tests and blood sugar level. This showed Neomune® yields no disadvantage and can be used in place of Traumacal® except that Neomune® had a significantly better result of triglycerides than Traumacal®. Furthermore, Neomune® consists of a lower amount of fat; as a result, this formula should be advised for patients with dyslipidemia.

SUMMARY

The present study concentrated on the comparison of immunoenhancing nutrition and current nutrition. The result shows immunoenhancing formula has no disadvantage and can be used as nutrition support. Moreover, during the first 9 days of immunoenhancing nutrition elevated some important amino acids, amount of protein, nitrogen balance and did not promote triglycerides level. Finally, Neomune® shortened ICU days and wean-off respirator days.

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การศึกษาผลของสูตรอาหารเพิ่มภูมิคุ้มกันเปรียบเทียบกับอาหารทางสายยางที่ใช้ในปัจจุบันในผู้ป่วยที่ได้รับบาดเจ็บรุนแรง

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ผู้ป่วยที่ได้รับอุบัติเหตุอย่างรุนแรงมักต้องการการรักษาอย่างรวดเร็ว ทั้งการช่วยฟื้นคืนชีพ การผ่าตัด การดูแลในด้านเมตาบอลิซึมและโภชนบำบัด เป็นที่ยอมรับแล้วว่า การให้โภชนบำบัดเป็นการรักษาที่สำคัญประการหนึ่ง ที่จะช่วยลดภาวะทุพโภชนาการ ป้องกันการเกิดภาวะภูมิคุ้มกันที่อาจจะลดลง และลดอัตราการเกิดภาวะแทรกซ้อน อันจะทำให้เวลาที่ผู้ป่วยอยู่ใน ICU สั้นลง และอัตราการอยู่โรงพยาบาลน้อยลง

วิธีการศึกษา : ได้ทำการศึกษาแบบ Prospective เพื่อดูผลของการให้โภชนบำบัดด้วยอาหารเหลวสูตรเพิ่มภูมิคุ้มกัน (Neomune) ซึ่งเป็นสูตรใหม่มีการเพิ่มสารกลูตามีน, อาร์จินีน และกรดไขมันประเภทโอเมก้าสามในอาหารที่ให้ทางสายยาง ทำการศึกษาในผู้ป่วยอายุระหว่าง 15–60 ปี ที่มารับการรักษาที่โรงพยาบาลศิริราช ซึ่งได้รับอุบัติเหตุที่มีความรุนแรงวัดด้วย Injury Severity Score (ISS) ระหว่าง 15–30 หรือมีไฟลวกเท่ากับ 30–60% ของพื้นที่ผิวกาย ผู้ป่วยถูกแบ่งแบบสุ่มเป็น 2 กลุ่ม กลุ่ม A ได้รับอาหารเป็น Traumacal กลุ่ม B ได้รับ Neomune โดยเริ่มต้นให้สารอาหารทางสายยาง (NG tube) ตั้งแต่วันที่ 2 หลังการบาดเจ็บ เริ่มให้สารอาหารความเข้มข้นครึ่งหนึ่ง จำนวน 30 มล.ต่อชม และเพิ่มขึ้นเป็นความเข้มข้นปกติ ตั้งแต่วันที่ 3 ถึงวันที่ 11 หลังการบาดเจ็บ จะเพิ่มปริมาณเป็นลำดับจนเท่ากับความต้องการของผู้ป่วย ประมาณ 80–100 มล.ต่อชม ทำการตรวจหา CBC, coagulogram, albumin, transferrin, CRP, LFT, BUN, Cr, CD_3, CD_{19}, CD_4, CD_8, CD_3, IgG, IgM, IgA และปริมาณกรดอะมิโน ในวันที่ 2, 6 และ 11 หลังการบาดเจ็บ ทำการเปรียบเทียบข้อมูลของผลการรักษารวมทั้งค่า Nitrogen Balance ของผู้ป่วยทั้งสองกลุ่มโดยใช้ Student *t*–test

ผลการศึกษา : ผู้ป่วย 36 ราย (อุบัติเหตุทั่วไป 16 ราย, ไฟลวก 20 ราย) เป็นชาย 29 ราย อายุเฉลี่ย 29.86 ปี ถูกแบ่งอยู่ในกลุ่ม A (Traumacal) 18 ราย กลุ่ม B (Neomune) 18 ราย, ข้อมูลที่ได้รับพบว่า กลุ่ม B มีปริมาณโปรตีนสูงขึ้น

อย่างมีนัยสำคัญในวันที่ 11 หลังการบาดเจ็บ (Neomune = 6.52 ± 1.29, Traumacal = 5.59 ± 1.21, p = 0.03) และมี positive nitrogen balance ที่ดีกว่าด้วย, ในวันที่ 11 หลังการบาดเจ็บ ผลของ Triglycerides ในกลุ่ม B ต่ำกว่าอย่างมีนัยสำคัญทางสถิติ (Neomune = 128.39 ± 53.45, Traumacal = 186.25 ± 84.07, p = 0.02), ส่วนข้อมูลผลการรักษา พบว่ากลุ่ม B มีจำนวนวันในการอยู่ ICU เท่ากับ 3.41 วัน, กลุ่ม A = 7.83 วัน และการใช้เครื่องช่วยหายใจน้อยกว่า (กลุ่ม B = 2.71 วัน, กลุ่ม A = 7.39 วัน) แต่ไม่มีนัยสำคัญทางสถิติ มีผู้ป่วยเสียชีวิตกลุ่มละ 1 ราย

สรุป : อาหารสูตรเพิ่มภูมิคุ้มกัน (Neomune) สามารถใช้กับผู้ป่วยที่ได้รับบาดเจ็บรุนแรงได้เท่ากับอาหารประเภทที่ใช้อยู่ในปัจจุบัน โดยไม่มีภาวะแทรกซ้อน ในขณะเดียวกันอาหารสูตรเพิ่มภูมิคุ้มกันยังช่วยเพิ่มปริมาณโปรตีนในร่างกาย ช่วยลดอัตราการอยู่ ICU และการใช้เครื่องช่วยหายใจได้ด้วย

คำสำคัญ : อาหารเพิ่มภูมิคุ้มกัน, กลูตามีน, อาร์จินีน, กรดไขมันโอเมก้าสาม, บาดเจ็บรุนแรง

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