

## ARTICLE

# A CLINICAL TRIAL TO COMPARE THE EFFICACY OF STANDARD PRODUCTS OF ENTERAL NUTRITION WITH CONVENTIONAL NUTRIENT SOLUTION TO IMPROVE THE PHYSICAL HEALTH IN DIABETIC PATIENT WITH ISCHEMIC HEART DISEASE

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## ABSTRACT



**Background:** CABG, Diabetic hospitalized patients show an increased rate in metabolic and catabolic processes, hyperglycemia, negative nitrogen balance, weight loss, muscle atrophy and multiple organ failure including gastrointestinal and respiratory failure. These events may be due to hormonal changes and the secretion of acute phase of the reactants. Therefore, this study aims to assess the effect of conventional nutrition in hospital (kitchen made), versus enteral nutritional therapy on several serum parameters in post-surgery diabetic patients to determine the preferred method to control these parameters. **Methods:** This prospective, randomized study was performed in a 14 months period on 35 diabetic patients between 18-72-years-old. The patients were randomly allocated into two groups to receive both conventional nutrition (Control Group) and enteral nutrition (Intervention Group). They were followed up for five days during admission in the hospital and after operation. In this study we have monitored the para-clinical parameters, such as fasting blood sugar (FBS), white blood cells (WBC), cholesterol, triglyceride, total protein, albumin & pre-albumin, blood urea nitrogen (BUN) and creatinine in three times, during their hospitalization. Also we have controlled their weight and general situation in mentioned period. The data were analyzed with SPSS version 18. **Results:** In our study some clinical parameters like: the concentration of serum albumine and pre-albumine in enteral group were significantly higher than control group. Also some parameters like: transferrin and total leukocyte count (TLC) were significantly lower in enteral group. By measuring these parameters, the count index showed the malnutrition in patients. As we used this Index in our study, malnutrition in intervention group (enteral), was significantly lower than control group. **Conclusion:** Some surgical patients need nutrition support for either pre- and or post-operatively due to the severity of their existing malnutrition or the presence of post-operative complications and hence prolonged delay in recovery of normal food intake. These patients should receive support by the simplest possible method using oral supplements, enteral tube feeding alone or mixed as necessary. In conclusion, the enteral method can provide more calorie and protein to post-operative, diabetic patients during their residency in hospital.

## INTRODUCTION

### KEY WORDS

Enteral Nutrition, CABG, Serum parameters, Ischemic Heart Disease, CONUT Index (Controlling Nutritional status Index).

Although the history of utilizing enteral feeding procedure for hospitalized patients goes back to the 70's, attentions have just been attracted to its concept and utilization again. Malnutrition is a common problem in about 40% of the patients and due to the absence of an accurate monitoring system and lack of an appropriate metabolic support methods particularly for patients in critical phase, these patients are usually exposed to nutrition dangers [1].

Providing a correct and appropriate nutrition and diet therapy services in hospitals is an important factor that enhances the recovery of the patients, make it shorter and even prevents the diseases. According to researches, if nutrition as one of the main elements for patients' health be ignored in the hospitals or if it doesn't play its significant role in therapeutic process, it will cause dissatisfaction among the patients and disrupt the process of treatment. For instance, un-informed selection of foods that increase the levels of blood cholesterol in cardio-vascular patients and decrease the calorie and protein in patients with burning or infection or increase blood sugar in diabetic patients, will increase the critical conditions of the patients and decrease the effectiveness of treatments [2].

In other words, these patients mostly die due to the problems of malnutrition and not the disease itself. Nutrition is has an important role to prevent these kind of problems.

When the patient is not able to swallow or when he has no appropriate level of consciousness (such as those in the ICU) or when he is not willing to eat food due to nausea or anorexia (patients with cancer or after a hard operation), nutrition interventions are mostly carried out through vessels or intestines [3].

One of the target groups of the hospitalized patients with severe malnutrition are diabetic heart ischemic patients that is due to intestinal atrophy caused by micro and macro-vascular complications, a rising flow of malnutrition procedure is observed.

During the time of staying in the hospital and after operation (CABG), these patients have problems such as anorexia, unable of swallowing, digestive system failure and incomplete absorption of food materials. As a result of body's metabolic response to stress, more nutrition materials will be needed for body [4].

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The best nutrition strategy in this situation with minimum complication which can provide the body of the patient with the most controlled nutrients is enteral formula nutrients. In this method, all the body required nutrients and water with a fixed and controlled nutritional value are sent to the digestive system by some tubes through mouth or nose. Despite the kitchen made feeding, this method helps us make sure that certain food stuffs with a certain level reach the patient's body. This is also a better method in terms of hygiene and health [5].

Those patients who are in the danger of insufficient feeding (malnutrition) are as follows: Oncological patients, ear, nose and throat patients, patients with chronic inflammatory bowel complications, neurological patients, those with AIDS, elderly patients with mental problems, those with chronic liver and kidney failures before and after operation. There are special formulations for each condition and situation [6].

There are different enteral formulas and plenty of products for diabetic patients. These formulations contain less carbohydrates and more fat in compared with standard formulations. Of course, the source of carbohydrate in these formulations is quite different. These sources are oligosaccharides fructose, corn starch and fiber [7].

Considering the introduction of complementary food products to medication baskets and supplemental materials and increasing popularity of them, we tried to measure and estimate the efficiency of such products.

The aim of the present study is to compare the metabolic effects of enteral products among post-surgery heart ischemic patients with a history of diabetes and the kitchen made foods. Particularly, the metabolic support methods common in therapeutic centers are never conducted on a standard basis. Thus, the necessity of conducting such a research was completely clear.

## MATERIALS AND METHODS

This random clinical trial study focused on the present state of diabetic patients undergoing CABG operation. The study lasted 14 months from March 2009 to May 2010 and it was conducted in Shahid Rajaie Heart Treatment and Education Center of Tehran.

Having studied the patients in terms of anthropometric parameters and collecting the medical history and conditions of inclusion in research, the patients were randomly divided into two groups. The first group (control) was fed on kitchen made food, while the second group (intervention) was fed on enteral foods.

### Patients' inclusion criteria

- 1) The patient should be older than 18 and be hospitalized in men's or women's operation unit.
- 2) The patient should not be able to eat normally and only enteral feeding method could be used for him/her.

### Patient's exclusion criteria

- 1) If the patient regains the ability to eat food while being hospitalized in the unit or during any stage of research.
- 2) If the patient dies or is discharged before the 5th day of his hospitalization.
- 3) Having liver or kidney problems.

The metabolic needs of the patients in intervention group were calculated individually according to Harris-Benedict equation:

$$\begin{aligned} \text{TEE (men)} &= 66.67 + (13.75 \times W) + (5 \times H) - (6.76 \times A) \times \text{Activity Factor} \times \text{Stress Factor} \\ \text{TEE (women)} &= 655.10 + (9.56 \times W) + (1.85 \times H) - (4.78 \times A) \times \text{Activity Factor} \times \text{Stress Factor} \end{aligned}$$

The following codes were defined for the patients: A for age in terms of years, W for weight in terms of kilograms, and H for height in terms of centimeter. The activity factor for all those patients hospitalized in the hospital was set to  $\frac{1}{2}$ . Each milliliter of the enteral solution contains 1/0 Kcal energy and in each 100 milliliter of solution, 83 milliliter of it is made of water. Having determined the daily level of TEE for each patient, the amount of the solution required by that person in one day was calculated and the amount of water and other liquids in it were determined. If the daily water required by the patient was more than what was supplied by the solution, this need was answered by adding an extra amount of water to the solution.

A group underwent enteral feeding (in the form of continuous feeding). This feeding was prescribed and conducted since the very first day the patient had entered the unit after operation.

It should also be noted that this clinical trial study was approved in the ethics committee of hospital of Rajaie Cardiovascular Medical and Research Center and all patients have been signed the secret consent form.

The patients in the witness group underwent Gavage according to the principles of Bolus in accordance with the usual procedure of hospital (without determining the amount of calorie required). The patients were studied and investigated during the five days period of research and study before operation, while beginning the feeding procedure (the first day after operation), the third and fifth day after operation in terms of serum albumin, pre-albumin, transferrin, total protein, serum lipids and fasting blood sugar (FBS), blood urea nitrogen (BUN) and creatinine and Maastricht index and CONUT (PI prognostic index).

Maastricht Index =  $20.68 - (0.24 \times \text{Serum Albumin (g/L)}) - (19.21 \times \text{Serum pre-albumin (g/L)}) - (1.86 \times \text{TLC (10}^6/\text{L)})$

Considering albumin indexes, number of total lymphocytes and cholesterol, a score would be given to the patients in count index [Table 1].

The method of calculating malnutrition using COUNT index:

**Table 1:** Assessment of under-nutrition degree by CONUT

Parameters	Under-nutrition degree			
	Normal	Light	Moderate	Severe
Serum albumin(g/dl)	3.5-4.5	3.0-3.49	2.5-2.9	<2.5
Score	0	2	4	6
Total Lymphocytes/ml	>1600	1200-1599	800-1199	<800
Score	0	1	2	3
Cholesterol(mg/dl)	>180	140-180	100-139	<100
Score	0	1	2	3
Screening total score	0-1	2-4	5-8	9-12

SPSS version 18 (SPSS Inc. Released 2009. PASW Statistics for Windows, Version 18.0. Chicago: SPSS Inc.) were used to analyze the data.

Quantitative variables were described in terms of mean  $\pm$  standard deviation, while qualitative variables were described in terms of their percentage. One sample Kolmogorov-Smirnov test was utilized were used to study the trend line of data with normal distribution, Information analysis was conducted using t-tests, chi square, and repeated measure ANOVA models.

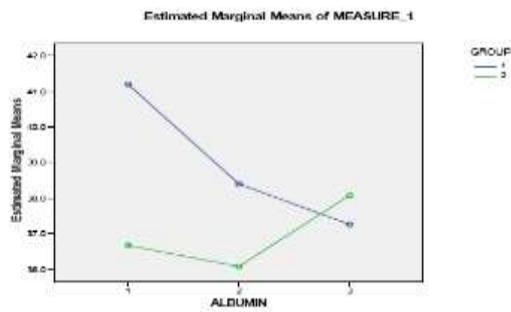
## RESULTS

The clinical and laboratory assessments were completed in 35 patients. Two patients from the intervention group could partially recover their eating capability. Two from the control group and one from the intervention group passed away. [Table 2] shows the demographic information of the patients [Table 2].

**Table 2:** The demographic information of the patients studied

	Intervention group N=15	Control group N=15	P-value
Age (years)	60.43 $\pm$ 9.788	62.13 $\pm$ 8.096	0.615
Gender (male and female)	Male Female	Male Female	
Ideal weight (kg)	62.95 $\pm$ 14.55	69.16 $\pm$ 14.45	0.061
Primary BMI (kg/cm <sup>2</sup> )	20.65 $\pm$ 5.05	22.78 $\pm$ 2.64	0.077

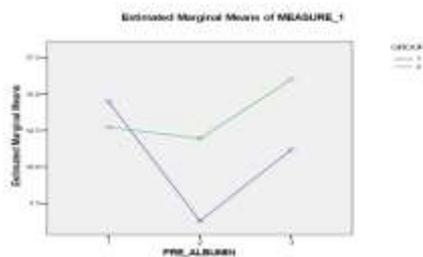
The changes in the serum albumin concentration was not significant in any groups (P-value = 0.30). The paired comparison of means between groups showed no significant difference (P-value > 0.05) [Fig. 1].



**Fig. 1:** Changes in the level of albumin in both groups over the course of time.

The general trend of pre-albumin changes during that period was significant among groups (P-value < 0.001). The comparison between the mean of this concentration in groups 1 and 2 demonstrated a significant difference with a P-value less than 0.001. Meanwhile, the mutual effect between groups and pre-albumin concentration was reported to be significant in various times (P-value < 0.001).

The trend of changing pre-albumin concentration from time 1 to 3 was not significant (P-value = 0.475), but the trend of change from time 1 to 2 and from 2 to 3 was significant (P-value < 0.001) [Fig. 2].

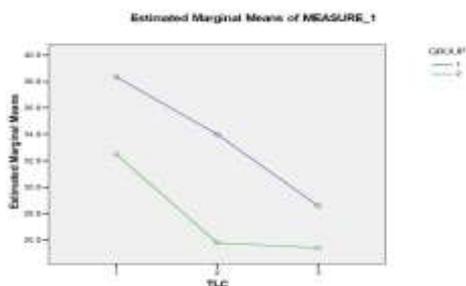


**Fig. 2:** Prealbumin changes in two groups over the course of time.

Total lymphocytes count was not significant while carrying out the research (P-value = 0.053). On the other hand, a comparison between the average total leukocyte count (TLC) of groups 1 and 2 showed no significant difference (P-value = 0.157).

The interactive influence of group and TLC was also reported to be significant (P-value = 0.02).

TLC changes over the courses of 1 to 2 and 2 to 3 were significant with P-values of 0.000 and 0.001 respectively. However, these changes were not significant in 2 to 3 period [Fig. 3].



**Fig. 3:** TLC changes over the course of time.

Changes in transferrin concentration was generally significant without causing any distinction (P-value = 0.030). Comparison of its mean between groups 1 and 2 shows a significant difference (P-value = 0.05). Changes from period 1 to 2 and from 1 to 3 were also reported to be significant (P-value < 0.01). However, no significant change was observed from time 2 to 3. This means that transferrin in both groups was different [Fig. 4].

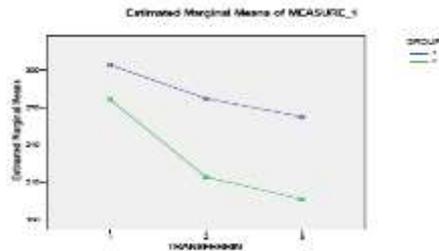


Fig. 4: Changes in transferrin concentration.

## DISCUSSION

In the present study, the status of the patients receiving ready and sterilized solutions which contain a certain level of nutrition materials was studied in terms of pre-albumin (as one of the best parameters to determine the nutrition support adequacy), and deterioration of nutritional status (OUNT). Prediction of the state and reduction of the possibility of death indicated a significant improvement in compared with the patients who received hospital gavage. COUNT index seems to be an adequate tool to quickly diagnose malnutrition and constantly control the patient while he/she is hospitalized.

Due to economic and cultural causes and, above all, lack of awareness of the importance of nutritional state of patients, kitchen-made solutions under the title of hospital gavage are used for those patients who are in the recovery stage. These solution contain natural nutrition such as milk, egg, meat, juice and vegetables in puree form. Hospital staff think that these solutions are theoretically capable of fulfilling the nutritional requirements of patients. The studies conducted in this field do not approve this idea [8].

In a research conducted in Saudi Arabia (2004) by Mokhalalati et al, [9] 18 samples of the solutions prepared in three hospitals were studied and compared against samples of pre-prepared and commercial solutions in terms of nutritional content, pollution and microbes (including counting the aerobic micro-organisms developed in the plate and checking the growth of micro-organisms) and physical properties such as viscosity and osmolarity. There was a certain pollution in all samples of gavage (with differences between hospitals). These samples were observed less frequently in commercial samples. Viscosity of Kitchen-made (Gavage) samples was 200 times as much as what was observed in other samples and their osmolarity was reported to be twice more than other samples [9].

In the studies previously conducted to compare Enteral and Conventional methods, five studies reported changes in measurement of nutritional parameters. Three researches indicated an improvement in the health of patients ( $P=0.001$  to  $P=0.05$ ), while two studies did not report any change between the two groups. Another study had reported a significant reduction of death in enteral nutrition group ( $P = 0.02$ ) [10-14].

This study showed a great frequency of malnutrition among post-surgery patients with a history of diabetes. It is recommended to form a team composed of doctor, hospital's pharmacist and a nutritionist in order to support the patients with appropriate nutritional support.

Thus, the present research aims to study the nutritional status of patients based on the above-mentioned criteria among two groups of people under standard enteral nutrition and compare it with those patients undergoing treatments with methods common in Iranian hospitals (using Kitchen made products).

## CONCLUSION

Enteral nutrition can provide the patients having malnutrition with more protein and calorie compared to the usual nutrition and food of hospitals and improve the physical and health status of the patients. It will also result in a lower death rate and shorted period of hospitalization of patients. However, studies with a longer follow up period and more population are required in order to achieve more reliable results.

### CONFLICT OF INTEREST

The authors declare no competing interests in relation to the work.

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### FINANCIAL DISCLOSURE

There is no financial disclosure.

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