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# STATISTICAL ANALYSIS OF RESULTS IN PATIENTS APPLYING THE SUSTAINABLE DIET INDICATORS

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### **Abstract**

The influence of the functional food and food supplements is of great importance not only to understanding the patients' needs, but also to improve the health and to fairly consider having a better and healthier lifestyle. Research on patient satisfaction regarding their physical appearance is very significant both for understanding their needs, as well as for objective consideration of their health by health professionals. It is an essential tool for health care improvement. Monitoring patients' health should be the focus of attention of all health professionals and nutritionists and shall become an imperative and indicator for further evaluation.

The research was conducted on a simple random sampling of 56 patients in the Dietetics and Nutrition Counseling Company "PROTEKTAL" in Skopje. They were monitored under strict medical supervision aimed at treatment of obesity. For this purpose, they were put on a very low calorie diet with a minimum input of 800 - 900 cal. daily, in small but frequent meals. This type of functional food is the protein food that contains bioactive peptides and proteins that meet the daily needs of intake of various foods rich in vitamins and minerals. For the statistical analysis of descriptive statistics and correlations, Statistica for Windows 7 and SPSS 17.0 were used. The comparison between the phases of male and female patients was performed with Student-test.

It was notable that after the first and second phase of the diet, the values of all parameters were significantly reduced. After the eight-month diet (for some patients even slightly longer), i.e., after all five phases of the diet, all parameters were back to normal and some were even lower than the reference values. The body mass (BM) among male decreased by an average of 34.7% and average decrease of 40.1% among female subjects; body mass index (BMI) decreased by 51.3%, while in the female population 43.4%. In male subject,

the chest circumference decreased by an average of 27.2%, and 30.9% by female population, while the waist circumference decreased by an average of 27.8%, and 30.3% among female subject. In male subjects, the high transaminase values (ALT) taken at the beginning of treatment decreased by an average of 40.7%, and in female subjects, by 29%. An average decrease in hepatic enzymes (AST) by 32.8% in male subjects and 32.3% in female subjects. The lipid status (HDL) values were reduced by an average of 18.5% in male patients and 23.5% in female subjects, while the total cholesterol values decreased by 25.2% on average in male subject, while in female subject it was by 24.9%. The triglycerides were reduced by 35.2% on average in the male group, and 29.1% in female subjects; Glucose was reduced by an average of 20.1% in male patients and 29.1% in female patients.

The results from t-test confirmed significant difference from the male/female results between the phases and before diet and after using the protein low calorie diet.

**Key words**: Bioactive proteins and peptides, Obesity, Patients, Medical care, Balanced diet, Nutrition.

## 1. Introduction

Human body uses energy for its biochemical needs, for its biosynthetic processes, for the mechanical work which it needs in the process of breathing and blood circulation, as well as for movement of muscles and their contraction. To put it simply, energy is the main trigger of the human body without which it could not exist. That is why, the United Nations (UN) has set the provision of sufficient amount of healthy food as one of the fundamental human rights [1].



According to the Yoshinori et. al., [2] functional food is the protein food that contains bioactive peptides and proteins that meet the daily needs by consuming various foods rich in vitamins and minerals. In ketosis, human body produces ketones at an accelerated rate. Ketones, or ketone bodies, are made by your liver from fat that one person eats and from own body fat. Thanks to the low carbohydrate intake, hypoinsulinaemia (low level of insulin in the bloodstream) occurs, which also causes lipolysis (decomposition of fat) [3, 4]. When glucose and insulin levels decrease on a carb-restricted diet, the liver ramps up its production of ketones in order to provide energy for human brain. Fatty acids oxidize into ketone bodies, which become source of energy having anorexic effect - absence of hunger and spiritual effect - good mood with a lot of energy. As a result of the foregoing metabolic changes, the protein diet is characterized by absence of hunger, good mood, rapid loss of body fat, and retention of muscles. The positive outcomes from this diet are: 100% a rapid weight loss essentially from fat; Retention of muscles; No hunger or anxiousness; Full of energy; Helps regulate blood sugar and cholesterol; No yo-yo effect; Compulsory medical supervision. The negative outcomes from this diet aren't existing.

The aim of this research is to examine the intake of nutrients and it is kind of quantitative analytical cross-sectional study.

#### 2. Materials and Methods

This research was implemented in the period from April 2016 to May 2017 in the Dietetics and Nutrition Counseling Company "PROTEKTAL" in Skopje, and it was conducted on a simple random sampling of 56 patients. They were monitored under strict medical supervision aimed at obesity treatment. For this purpose, they were put on a very low calorie diet with a minimum input of 800 - 900 cal. daily, in small, but frequent meals. This type of functional food is the protein food that contains bioactive peptides and proteins that meet the daily needs by consuming various foods rich in vitamins and minerals [5, 6]. More precisely, protein diet was a low-calorie, low-fat diet (10 g of olive oil to protect contractility of the gallbladder and polyunsaturated fats Omega 3 for lipo-inflammation suppression) with intake of proteins adapted to the daily need of the body (0.8 - 1.2 g/kg for ideal weight) based on high biological value proteins and intake of carbohydrates below 50 g daily, thus leading to entry into ketosis.

For the statistical analysis of descriptive statistics and correlations, Statistica for Windows 7 and SPSS 17.0 were used [7, 8]. The comparison between the phases of male and female patients was performed with Student-test [9, 10]. The level of significance, confidence coefficient, and two-tailed or one-tailed test during

analysis are specified. Usually, 5% is used as the levels of significance and 95% as confidence coefficient. In testing, it is described, difference is significant with significant probability (p value).

#### 3. Results and Discussion

In fact, this research is a quantitative cross-sectional study implemented over a period of eight months at the dietetics and nutrition counseling company in Skopje. Research was conducted on a simple random sampling of patients who, during the period of their weight reduction, came for an examination at the counseling company. The research covered all patients meeting established criteria for participation in this research and they participated in the whole research process. Criterion for exclusion were patients with diabetes mellitus 1, or patients on regular insulin therapy, patients with diabetes mellitus 2 in current insulin treatment, and patients with renal and hepatic failure. The total number of patients was 56, 26 of which were males and 30 were females. Analyzed parameters were: of blood count, glucose, lipid and enzyme status, transaminases, height, weight, BMI, bust/chest circumference, waist circumference. Results were recorded for each patient in a medical record. The patients were monitored over an eight-month treatment.

Representation of anthropometric parameters of the patients are given according Hiemstra *et al.*, [11], and Newby *et al.*, [12]. Overview of anthropometric parameters of the patients (56) taking part in the research as: BMI is body mass index (kg/m²); BM is body mass (kg); O-1 - bust (cm); O-2 - waist. Phase 1 represent initial state, phase 3 represent state between phase 1 and 5, and phase 5 represent state after the diet (Table 1 and Figure 1).

As is showed, the BMI (Body Mass Index) decreased by 51.3%, while in the female population, the average decrease of BMI was 43.4%. The Body mass (BM) among male subject decreased by an average of 34.7% compared to an average decrease of 40.1% among female subjects. The chest circumference (O-1) decreased by an average of 27.2%, compared to female subject whose bust circumference decreased by 30.9%. In male subjects, the waist circumference (O-2) decreased by an average of 27.8%, compared to an average decrease of 30.3% among female subject. Comparison between the phases1 and 5 of male and phases1 and 5 of female patients was performed with Student-test. From the conducted T-test where is p < 0.05 the values of the parameters (BMI, BM, O-1, O-2) of phase 1 and phase 5 are statistically significantly different, which confirms the success of the diet.

Biochemical parameters of the patients as: ALT - (U/L); AST - (U/L); HDL - (mmol/L); LDL - (mmol/L) are presented the Table 2 and Figure 2.



Table 1.Representation of the 56 patient's parameters (males and females)

Subjects	BMI (average value)	Δ (%)	BM (average value)	Δ (%)	O-1 (average value)	Δ (%)	O-2 (average value)	Δ (%)
Phase 1	53.1	/	130.7	/	121.1	/	135.9	/
Phase 3	/	/	90.0	-31.1	93.4	-22.8	104.6	- 23.0
Phase 5	27.9	- 47.3	81.5	- 37.6	85.7	-29.1	96.3	- 29.1
Representation of the 26 male patient's parameters								
Phase 1	61.5	/	141.6	/	131.8	/	147.6	/
Phase 3	/	/	100.6	- 28.9	104.1	- 21.0	115.5	- 21.7
Phase 5	29.9	- 51.3	92.3	- 34.7	95.9	- 27.2	106.4	- 27.8
Representation of the 30 female patient's parameters								
Phase 1	46.6	/	122.4	/	112.8	/	127	/
Phase 3	/	/	81.8	- 33.1	85.1	- 24.5	96.3	- 24.1
Phase 5	26.4	- 43.4	73.2	- 40.1	77.9	- 30.9	88.5	- 30.3

Table 2. Biochemical parameters of the patients (56) taking part in the research (ALT, AST, HDL, LDL)

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Subjects	ALT (average value)	Δ (%)	AST (average value)	Δ (%)	HDL (average value)	Δ (%)	LDL (average value)	Δ (%)
Phase 1	39.7	/	29.4	/	1.21	/	3.32	/
Phase 3	32.6	- 17.8	23.6	-19.5	1.02	- 15.8	2.87	- 13.5
Phase 5	25.4	- 35.8	19.8	-32.5	0.89	-26.3	2.6	- 21.3
Representation of the 26 male patient's parameters								
Phase 1	53.0	/	34.6	/	1.1	/	3.26	/
Phase 3	43.7	- 17.5	28.7	-17.1	-0.9	- 15.7	2.7	- 15.4
Phase 5	31.4	- 40.7	23.2	-32.8	-0.8	- 27.1	2.4	- 23.5
Representation of the 30 female patient's parameters								
Phase 1	29.4	/	25.4	/	1.3	/	3.3	/
Phase 3	24	- 18.2	19.8	-21.9	1.0	- 15.8	2.9	- 12.1
Phase 5	20.8	- 29.0	17.1	-32.3	0.9	- 23.5	2.7	- 19.7

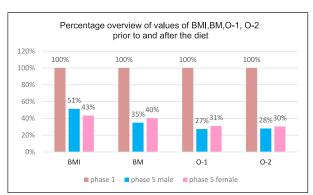
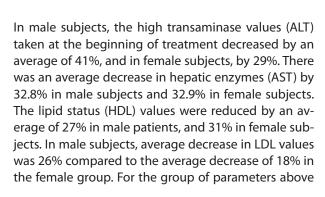
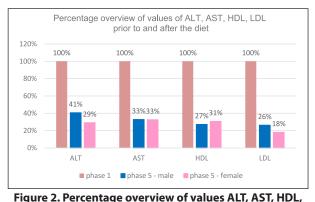


Figure 1. Percentage overview of values prior to (phase 1) and after the diet (phase 5)





LDL, prior to (phase 1) and after the diet (phase 5)

(ALT, AST, HDL, LDL) T-test was conducted. We compared average values of parameters of the phases1 and 5 of male, and phases1 and 5 of female patients. Probability value of T-test is p < 0.05 for all parameters, which mean phase 1 and phase 5 are significantly different. T-test again confirms the success of the diet. probability value.

In the Table 3 and Figure 3 is presented an overview of the following biochemical parameters: cholesterol, triglycerides, glucose (mmol/L).



Subjects	Chol. (average value)	Δ (%)	TG (average value)	Δ (%)	Glucose (average value)	Δ (%)			
Phase 1	5.9	/	1.9	/	5.8	/			
Phase 3	- 5.0	- 14.5	- 1.5	- 21.9	- 5.2	- 10.8			
Phase 5	- 4.4	- 25.0	- 1.2	- 37.7	- 4.8	- 16.8			
Representation of the 26 male patient's parameters									
Phase 1	5.8	/	2.7	/	6.3	/			
Phase 3	- 5.0	- 13.3	- 2.0	- 24.6	-5.7	- 10.1			
Phase 5	- 4.3	- 25.2	- 1.5	- 43.5	-5.0	- 20.1			
Representation of the 30 female patient's parameters									
Phase 1	6.0	/	1.4	/	5.4	/			
Phase 3	- 5.0	- 15.4	- 1.1	- 17.7	-4.8	- 11.4			
Phase 5	- 4.4	- 24.9	- 1.0	- 29.1	-4.7	- 13.9			

Table 3. Biochemical parameters of the patients: cholesterol, triglycerides, glucose

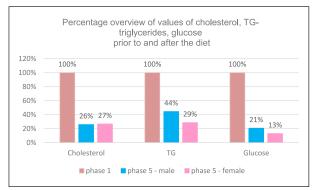


Figure 3. Percentage overview of values (cholesterol, TG- triglycerides, glucose), prior to (phase 1) and after the diet (phase 5)

Figure 3 displays percentage overview prior to (phase 1) and after the diet (phase 5). Total cholesterol values in male subjects decreased by 26% on average, while in female subject it was by 27%. Triglycerides were reduced by 44% on average in the male group, and 29% in female subjects. Glucose was reduced by an average of 21% in male patients and 13% in female patients. Probability value of T-test is p < 0.05 for all parameters, which again means that phase 1 and phase 5 are significantly different. T-test again confirms the diet success.

#### 4. Conclusions

- Based on the analysis of the results obtained during the dietary research, it was confirmed that the condition of severe obesity, characteristic for the subjects at the beginning of the treatment, is related to developmental and health complications. In all subjects, irrespective of the gender, the values of anthropometric and biochemical parameters at the beginning of the research were significantly higher than the normal reference values. Hypertension (HTA) was established in all subjects, and hyperholesterolemia was reported in

three male patients and one female subject. Moreover, cholelitiasis was also reported in one female subject. Steatosis was observed in three male subjects and three female subjects. There was no case of *Helicobacter pilory* in male subjects, and there was one case in female subjects. Hypotireodosis status was present in 3 female subjects, while no male cases were registered. Hereditary diabetes was reported in 3 male patients and 6 female patients. Hidden diabetes was diagnosed only in one female patient, which was a criterion for exclusion. It was notable that female population had increased their body mass especially after childbirth, as opposed to the very small number of subjects who were overweight before pregnancy.

- After the first and second phase of the diet, the values of all parameters were significantly reduced. After the eight-month diet (for some patients even slightly longer), i.e, after all five phases of the diet, all parameters were back to normal and some were even lower than the reference values.
- In order to pursue with this continuum of weight loss and to stop weight gain, it is necessary to follow the recommendations of the doctor/nutritionist and to have periodic checks. In the meantime it is permissible to consume all kinds of food, but in moderate amounts.
- The purpose of this diet is not to skip meals, but to adapt the body to consuming small but more frequent meals, [13]. This means that the diet of our grandparents who ate less, but more often, should be applied. This way, the digestive system is not burdened, the endocrine glands can function (excrete) smoothly and effortlessly, there is no need to burn fat, no stimulation of insulin shall be needed, etc. So, eating healthy, quality food meals, not less than five a day, and consuming them every three to four hours, ensures proper weight distribution, without fear of regaining fat or having other side effects, the most undesirable of which, of course is, the so-called yo-yo effect.



### 5. References

- [1] Moran A. L., Horton A. R., Scrimgeour G., Perry M. (2011). Leninger Principles of biochemistry. Pearson, London, UK.
- [2] Yoshinori M., Li-Chan E., Jiang B. (2010). *Bioactive Proteins and Peptides as Functional Foods and Nutraceuticals*. Wiley-Blackwell, New Jersey, USA.
- [3] Guo M. (2009). Functional foods: Principles and technology. Elsevier Science, the Netherlands.
- [4] Howlett J. (2008). Functional Foods from Science to Health and Claims.
   <URL: https://ilsi.eu/wp-content/uploads/sites/3/2016/ 06/C2008Func\_FoodEng.pdf. Accessed 10 February 2020.
- [5] Veech R. L., Chance B., Kashiwaya Y., Lardy H. A., Cahill G. F. Jr. (2001). *Ketone Bodies, Potential Therapeutic Uses*. IUBMB Life, 51, pp. 241-247.
- [6] Moore J., Westman C. M. D. (2014). Keto Clarity. <URL: https://www.scribd.com/document/412124479/ Keto-Clarity-by-Jimmy-Moore-and-Eric-Westman-MD. Accessed 8 February 2020.
- [7] Voidăzan S., Moldovan C., Dobreanu M. (2014). Suggestions and recommendations on statistical analysis and research methodology. Revista Română de Medicină de Laborator, 22, 4, pp. 413-418.
- [8] BMJ. (2020) Study design and choosing a statistical test. <URL: https://www.bmj.com/about-bmj/resources-read-ers/publications/statistics-square-one/13-study-design-and-choosing-statisti. Accessed 10 February 2020.</p>
- [9] Garmendia G. L. J., Monserrat M. F. (2018). *Interpretation of statistical results*. Med. Intensiva, 42, pp. 370--379.
- [10] EMEA. (2006). ICH Topic E 9: Statistical Principles for Clinical Trials.
  <URL: https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e-9-statistical-principles-clinical-trials-step-5\_en.pdf. Accessed 10 February 2020.</li>
- [11] Hiemstra B., Keus F., Wetterslev J., Gluud C.,Van der Horst I. (2019). DEBATE-statistical analysis plans for observational studies. <URL: https://bmcmedresmethodol.biomedcentral.com/ articles/10.1186/s12874-019-0879-5.
- [12] Newby, P, Weismayer, C, Åkesson, A.(2006). Longitudinal changes in food patterns predict changes in weight and body mass index and the effects are greatest in obese women. J. Nutr., 136, pp. 2580-2587.
- [13] Westman E. (2013). *A low Carbohydrate, Ketogenic Diet Manual: No Sugar, No Starch Diet.* CreateSpace Independent Publishing Platform, California, USA.