

Effects of Poly-N-acetyl-glucosamin associated to a hypocaloric diet on weight loss and hyperlipidemia control in obese patients.

RAVARA L., ALCANTARA C., ALCANTARA A.P., MOREIRA C.

Internal Medicine Unit. Santa María Hospital.
Lisbon University Medicine Faculty, October 2001.

Abstract

The study was performed in order to evaluate the effectiveness and tolerance of a new fiber based on Poly-N-acetyl- glucosamin, fructo-oligosaccharides and sodium ascorbate, associated to a hypocaloric diet in a three-month weight-loss program.

A randomized, double-blind and placebo controlled study was performed with 48 obese patients that were randomly distributed in two groups: a group A (control) that was treated with a hypocaloric diet (1000 kcal.) and a group B that was treated with the same hypocaloric diet and BioNarval.

The study shows a significant statistical reduction in weight, systolic pressure, total cholesterol, LDL cholesterol, triglycerides, as well as an increase in HDL cholesterol in both groups, reductions being significantly greater in the group treated with BioNarval than in the control group (body weight of 91.2 Kg. to 79.2 Kg. in group B and from 89.7 Kg. to 83.8 Kg. in group A; systolic pressure of 138.2 mm Hg to 129.3 mm Hg in group B and from 139.4 mm Hg to 130.1 mm Hg in group A; cholesterol total from 302.4 mg/dl to 232.6 mg/dl in group B and from 289.3 mg/dl to 268.4 mg/dl in group A; LDL from 206.8 mg/dl to 188.3 mg/dl in group B and from 203.4 mg/dl to 192.4 mg/dl in group A; triglycerides from 252.3 mg/dl to 196.3 mg/dl in group B and from 243.1 mg/dl to 202.4 mg/dl in group A; HDL from 27.3 mg/dl to 30.9 mg/dl in group B and from 26.8 mg/dl to 28.2 mg/dl in group A).

No significant modification of clinical or pathological order was observed in the hematology field.

Side effects were light and passing (flatulence) for 4.1% of the subjects treated with BioNarval® and for 12.3% of the subjects in group A (nausea and constipation) with no significant differences between both groups.

The study revealed that the diet associated to BioNarval® intake is very useful in treating overweight and obesity and that this weight loss is associated with an evident reduction of hyperlipidemia.

1. Introduction

Poly-N-acetyl- glucosamin is a natural substance, it comes from marine plankton with a 99% molecular purity and is presented in 100 Mesch microparticles, which translates in greater effectiveness, since its lipid absorption capacity increases with the increase in adsorption surface.

The lipid absorption process is due to Poly-N-acetyl- glucosamin dissolving in the acid medium of the stomach after ingestion, which allows the active ingredient to present an amino group with a positive charge, which binds to the fatty acids or to the biliary acids that have a carboxylic group with a negative ionic charge. Neutral fats (cholesterol and triglycerides) are bound by hydrophobic forces. Once both molecules have combined, it

is unviable for this new macromolecule to be absorbed, thus traveling through the digestive system, being finally eliminated with feces.

Sodium ascorbate, in its biochemical transformation to ascorbic acid, produces a synergic action with N-Acetyl glucosamin. It stabilizes lipid macromolecules preventing their absorption.

Fructo-oligosaccharides improve intestinal transit, favoring lipid elimination, and due to their bifidogenic action they achieve a natural balance of the bacterial flora

2. Aim

The aim of the study was to evaluate the effectiveness and tolerance of BioNarval associated to a hypocaloric diet in a weight loss program in obese subjects.

3. Materials and methods

The study was randomized and double-blind.

It was performed following the Helsinki World Medical Assembly and according to European Community quality, effectiveness and safety regulations for drugs for human use (91/507/CEE).

The study was performed with 48 adult patients of ages comprised between 25 and 76 years of age (46.6 ± 22.2 years old) of both sexes (18 men and 30 women).

Inclusion criteria

Valid subjects from 20 to 70 years of age with moderate obesity (overweight between 10 and 25% on weight and size normality tables) and with hyperlipidemia.

Exclusion criteria

Patients affected by revealed or supposed hypersensitivity to any of the product compounds. Patients not guaranteeing complete adherence to the study protocol, hepatic or gastrointestinal conditions, renal failure, severe chronic diseases, pregnancy, concomitant administration of drugs or substances that may interfere with study results.

Patients were randomly distributed in two groups with the same number of subjects (Table 1) being comparable by age, sex, weight, stature, total HDL and LDL cholesterol and triglycerides.

The usual dose of BioNarval was administered before main meals (lunch and dinner) for 3 months with an approximately 1000 Kcal associated diet.

After the first 3 months each subject was evaluated for: weight, blood pressure and side effects, evaluating both their seriousness and duration and the patient's quality of life.

At time 0 and at the end of the study blood analyses were performed determining hemoglobin, hematocrit, blood formula, glucemia, urea, creatinine, bilirubin, transaminases, gamma GT, sodium and potassium.

The statistical program used was SPSS v 10.1(P=0.25) (Student's t-test, Chi-square and Fisher's test).

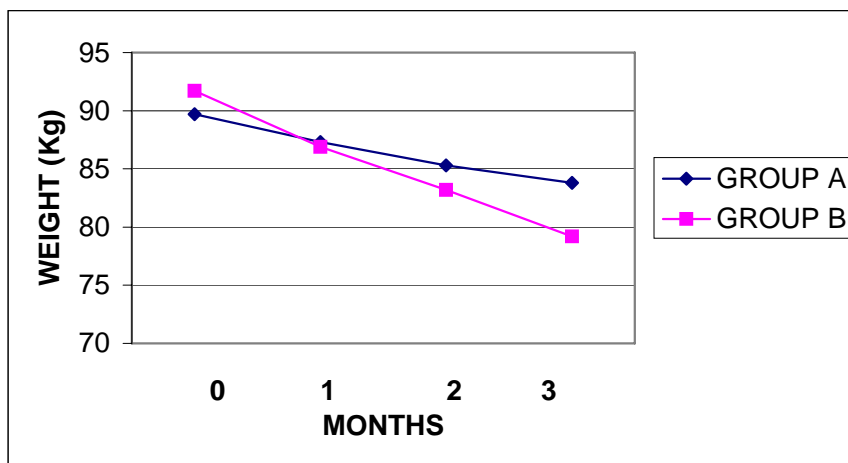
4. Results

Treatment adherence was very good, with no withdrawals in any of the two groups. The results are collected in the following table:

Weight determination*

WEIGHT (Kg)	GROUP A	GROUP B
Month 0	89.2±10.2	91.2±11.2
Month 1°	87.2±10.2	86.2±9.2
Month 2°	85.2±9.2	83.2±8.2
Month 3°	83.2±8.2	79.2±7.2
Total weight loss	5.2 Kg	12.2 Kg

- In weight determinations as well as in blood determinations for groups A and B, probability was less than 0.01 (P=0.05 significant difference using Student's t-test, Chi-square and Fisher's test).



The study shows a statistically significant decrease in weight, total cholesterol, LDL and triglycerides as well as an increase in HDL in both groups, but more noticeably in the diet with BioNarval (Table 2)

Side effects were slight and passing with flatulence in 4.2% of patients with BioNarval and in 12.2% in subjects treated only with hypocaloric diet that presented nausea and/or constipation, without a significant difference in product tolerance.

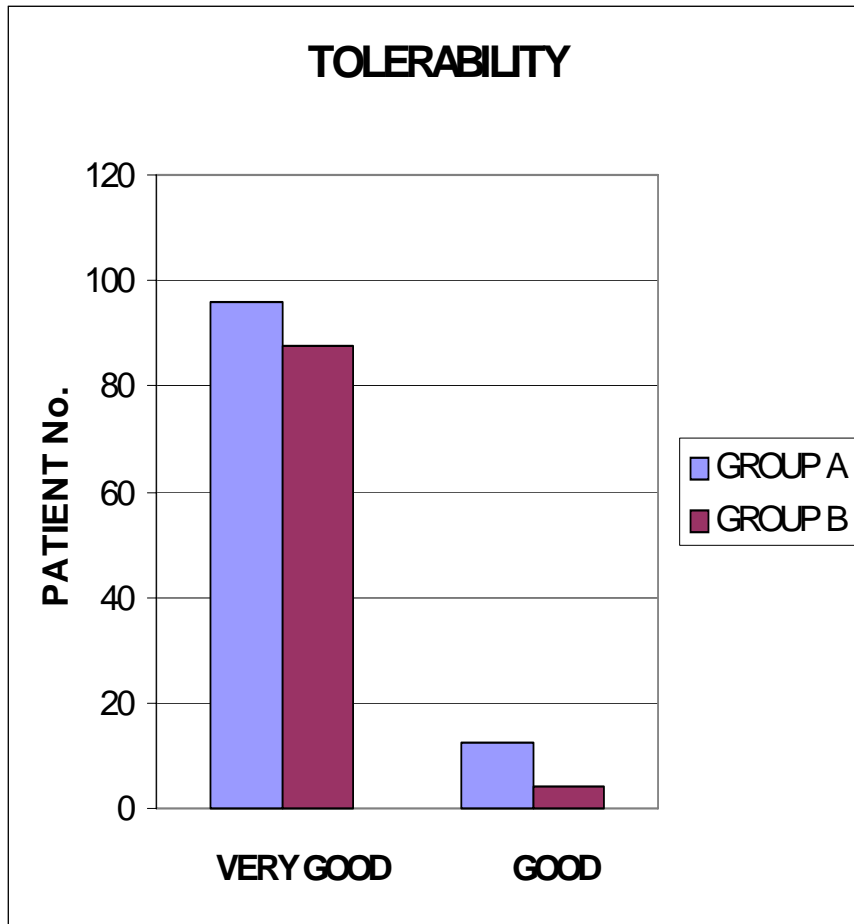


Table 1: Characteristics of patients included in groups A and B

	GROUP A	GROUP B
PATIENTS	24	24
MALE	8	10
FEMALE	16	14
AGE (YEARS)	45.2±17.2	43.2±18.2
HEIGHT (CM)	165.2±7.2	168.2±6.2
WEIGHT (KG)	89.2±10.2	91.2±11.2
TOTAL CHOLESTEROL (mg/dl)	289.2±40.2	302.2±38.2
HDL (mg/dl)	26.2±11.2	27.2±10.2
LDL (mg/dl)	203.2±43.2	206.2±42.2
TRYGLICERIDES (mg/dl)	243.2±36.2	262.2±38.2

Comentario:

Table 2: Parameter determination during the study*

PARAMETER	GROUP A		GROUP B	
	0 MONTHS	3 MONTHS	0 MONTHS	3 MONTHS
CHOLESTEROL (mg/dl)	289.2±40.2	268.2±35.2	302.2±38.2	232.2±28.2
HDL (mg/dl)	26.2±11.2	28.2±10.2	27.2±10.2	30.2±10.2
LDL (mg/dl)	203.2±43.2	192.2±39.2	206.2±43.2	188.2±38.2
TG (mg/dl)	243.2±36.2	202.2±37.2	252.2±38.2	196.2±38.2
HB (g/dl)	13.2 ±1.2	13.2 ±1.2	13.2±1.2	13.2±1.2
Ht (%)	43.2 ±5.2	44.2±6.2	44.2±6.2	43.2±5.2
GLUCOSE (mg/dl)	97.2±10.2	94.2±9.2	93.2±9.2	88.2±8.2
CREATININE (mg/dl)	0.24±0.24	0.26±0.26	0.23±0.29	0.29±0.27
AST (U)	25.2±6.2	27.2±5.2	30.2±7.2	30.2±6.2
ALT (U)	31.2±7.2	32.2±8.2	29.2±6.2	28.2±8.2
URIC ACID (mg/dl)	4.2±1.2	4.2±1.2	3.2±0.2	3.2±1.2
SBP (mm Hg)	139.2±7.2	130.2±6.2	138.2±8.2	129.2±8.2
GAMMAGT (mg/dl)	19.2±2.2	18.2±2.2	19.2±3.2	18.2±2.2
SODIUM (mEq/l)	138.2±9.2	138.2±10.2	140.2±10.2	140.2±11.2
POTASSIUM (mEq/l)	4.2±0.2	4.2±0.2	4.2±0.2	4.2±0.2

* In weight determinations as well as in blood determinations for groups A and B, probability was less than 0.01 (P=0.05 significant difference using Student's t-test, Chi-square and Fisher's test).

Conclusions

- The study confirms that BioNarval inclusion associated to a hypocaloric diet in a weight-loss program in obese patients allows a significant reduction of weight as well as of total cholesterol, LDL and triglycerides and a marked increase in HDL.
- These actions are due to the reduction in lipid absorption and their greater elimination through feces, which is greater in diets with BioNarval and comparable to the results obtained with colestiramin but with greater tolerance for BioNarval, which seems to be a SAFE and EFFECTIVE product that can be useful in combinations with hypocaloric diets for weight reduction in cases of obesity.

Scientific Publications

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