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Modification of metabolic syndrome parameters following the administration of polyglucosamine L112: results of a subgroup analysis of subjects enrolled in a double blind randomised placebo controlled clinical investigation

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Abstract

Background Up to now, scientific literature has not reported studies evaluating the efficacy of polyglucosamine L112 on body weight, insulin resistance, and cholesterol levels in patients with metabolic syndrome, despite its known antioxidant properties and potential to reduce these parameters, making it a promising candidate for treating metabolic syndrome.

Objective The aim of this study was to examine the activity of L112 in a subgroup of cases suffering from metabolic syndrome (MS).

Methods A subgroup of 26 subjects (8 males and 18 females; age 55 ± 11.3 years; BMI 31.1 ± 1.35 kg/m^2) was selected from a previous larger RCT study and statistically analyzed. Among them, 12 subjects were administered a diet and placebo, while 14 were administered a diet and L112 at a dosage of 3 g/day.

Results In the placebo group, 3 out of 12 cases (25%) showed resolution of metabolic syndrome (MS), whereas in the L112 group, 7 out of 14 cases (50%) showed resolution. Differences were statistically significant (Fisher $\chi^2 p < 0.01$). L112 was more effective than placebo on the reduction of BMI, BW, insulin resistance, visceral adipose tissue (VAT), and fat mass (FM). No modification of fat-soluble vitamins (Vit A, E, D3, K1) and glucosamine levels was shown.

Conclusions Despite a relatively short period of administration (3 months), L112 was found to reduce MS in 50% of the cases, acting as a safe medical device as a single daily treatment.

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Trial registration Current Controlled Trials NCT04375696, 20/12/2021 (https//clinicaltrials.gov/study/NCT04375696), "Retrospectively registered".

Highlights

- To date, no study has been conducted to evaluate the efficacy of polyglucosamine L112 on body weight, insulin resistance, and cholesterol in patients with metabolic syndrome, although the activities of polyglucosamine (antioxidant and reduction of BW, insulin resistance, and cholesterol levels) make this medical device an ideal candidate for the treatment of metabolic syndrome.
- Given this background, the aim of the present investigation is to analyze the activity of L112 versus placebo on body weight, insulin resistance, and cholesterol levels in a group of patients suffering from MS according to ATP III [1].

Keywords Polyglucosamine L112, Metabolic syndrome, Insulin resistance, Visceral adipose tissue, Fat mass, Fat-soluble vitamins

Introduction

Metabolic syndrome (MS) forms a cluster of metabolic dysregulations that encompasses multiple genetic and acquired entities that fall under the umbrella of insulin resistance [2].

Given that CVDs constitute the leading cause of morbidity and mortality worldwide, it has become essential to investigate the role played by MS in this context to reduce the heavy burden of the disease [3].

However, there is no single treatment for MS, and lifestyle modifications are required together with the currently available pharmacotherapy of related comorbidities. For these reasons, new therapies characterized by multiple activities are needed [4].

Fiber intake is known to be associated with BW reduction [5] and increases the transit time of the feces [6].

L112 is a Medical Device consisting of a cationic fiber that, in acidic medium, allows the formation of high-affinity bonds with lipid molecules present in the gastrointestinal lumen, decreasing their bioavailability. Once the gastric chyme reaches the duodenum, the pH increase transforms the combination of chitosan and the bound products into a gel, further limiting the absorption of the components.

Structurally, L112 is a chitin derivative extracted from the exoskeleton of crustaceans and consisting of unbranched polymers of beta (1,4)-D-glucosamine, in which the chains are stabilized by hydrogen bonds. The network of polymers in L112 is biocompatible and capable of efficiently binding and other food components fats [7, 8] as shown in Fig. 1. In this way, large, poorly digestible lipid-chitosan-starch emulsions are created, which are partly eliminated and partly used as a substrate by the bacteria present in the colon.

The lipases and colonic bacteria release fatty acids and metabolize them into products used for bacterial-membrane formation and as a source of energy [9]. Due to this activity, L112 treatment does not cause steatorrhea, and fat excretion in feces remains minimal.

Pharmacological studies have shown that polyglucosamine reduces BW and increases fat excretion in feces, particularly acetate [10, 11].

This aspect is significant because acetate drives insulin secretion, thereby promoting metabolic syndrome [12]. Furthermore, the high polarity of acetate enhances its binding affinity to L112 compared to long-chain lipids or cholesterol. This activity reduces acetate availability for the brain and decreases ghrelin secretion.

A recent meta-analysis, including 399 subjects (ages ranging between 21 and 75 years, and a BMI between 26 and 45 kg/m2) followed for a period ranging from 12 weeks to 1 year, showed that L112 supplementation improved weight loss, decreased BMI, and improved abdominal circumference (AC) [13].

In another meta-analysis [14], chitosan was shown to modify glycemic levels in people with metabolic syndrome following a treatment for at least 13 weeks at 1.6–3 g/day.

In a recent investigation on L112 [15], it was shown that this substance-based medical device administered in tablets before the main meals allows a significant reduction of BW, insulin resistance, and cholesterol levels without the modification of fat-soluble vitamin and glucosamine levels.

Moreover, polyglucosamine has been shown to reduce oxidative stress by limiting lipid oxidation and deposition in arterial walls and by modulating the intestinal absorption of dietary fats. This effect is particularly beneficial in reducing early signs of atherosclerosis and promoting cardiovascular health. This mechanism contributes to the prevention of subclinical atherosclerosis progression and improves arterial wall morphology, as evidenced by reduced carotid intima-media thickness (IMT) in clinical studies [16].

Metabolic syndrome (MS) and oxidative stress are closely interconnected, with oxidative stress acting as both a cause and consequence of MS components such as obesity, insulin resistance, hypertension, and

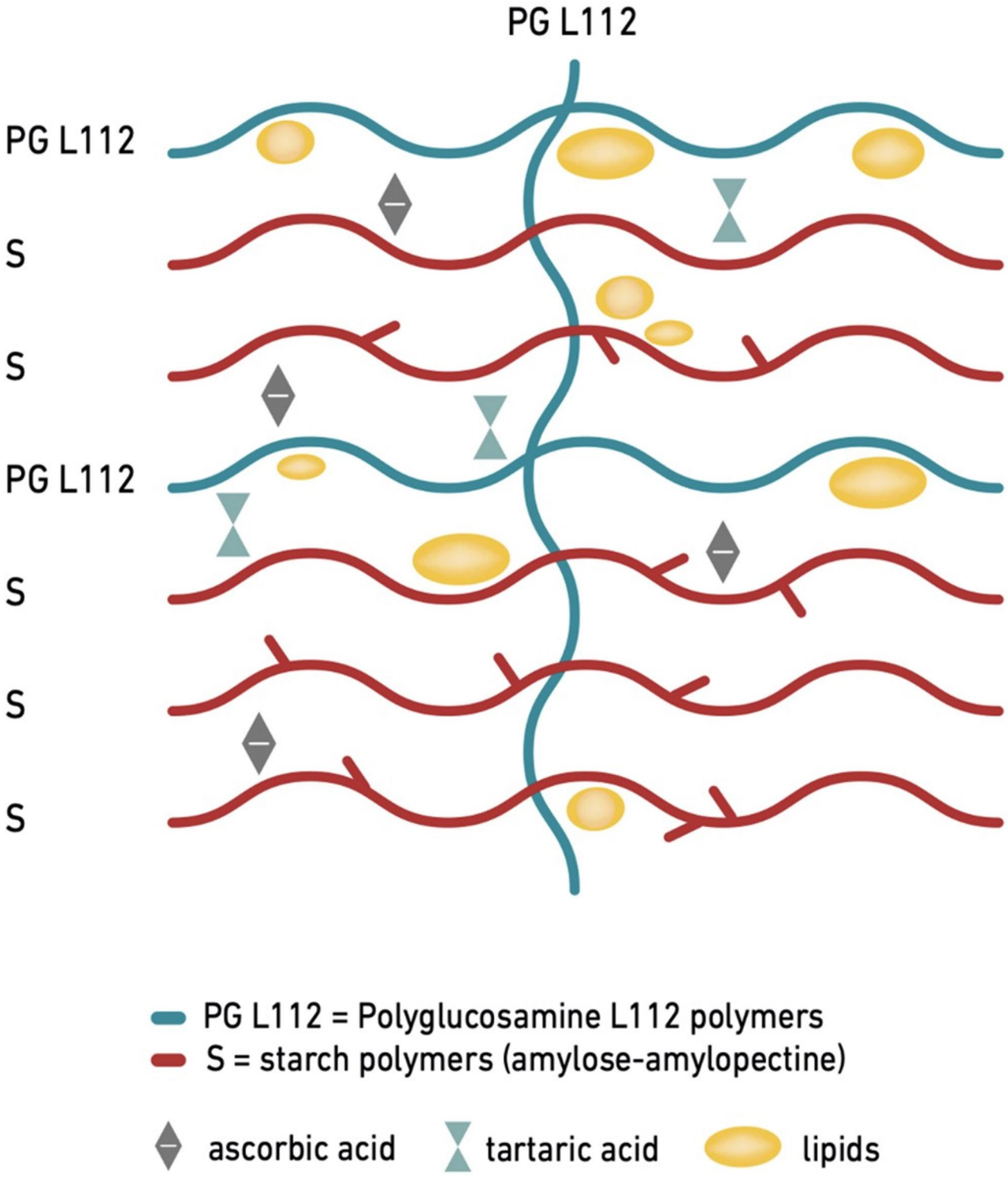

Fig. 1 Chitosan binding with some food components in the stomach

dyslipidemia. This relationship creates a vicious cycle that exacerbates metabolic dysfunction and increases cardiovascular risk [17].

To date, no study has been conducted to evaluate the efficacy of polyglucosamine L112 on body weight, insulin resistance, and cholesterol in patients with metabolic syndrome, although the activities of polyglucosamine (antioxidant and reduction of BW, insulin resistance, and cholesterol levels) make this medical device an ideal candidate for the treatment of metabolic syndrome.

The studies conducted have considered only the efficacy of chitosans on MS and were limited to blood glucose [14]. Polyglucosamine L112 instead consists of standardized polymers characterized by >80% dgree of deacetylation and a peak molecular weight (Mp) of about 65 KDa and was shown active on body weight, cholesterol levels and insulin resistance [15]. Based on this background, the present study aims to evaluate the effects of polyglucosamine L112 compared to placebo on body weight, insulin resistance, and cholesterol levels in patients diagnosed with metabolic syndrome (MS) according to ATP III criteria [1].

Methods

The original clinical investigation [15] can be summarized as follows: randomized double-blinded placebo-controlled study approved by the Bioethical Committee of IRCCS San Matteo hospital (protocol number 15012020), according to ISO (International Organization for Standardization), in GCP following ICH (International Council Harmonization), and registered with ClinicalTrials.gov (NCT04375696, Registration Date: December 20, 2021).

Participants were patients belonging to the dietetic and endocrinology unit of the Santa Margherita Institute (Pavia-Italy) aged between 18 and 65 years with BW (Body Weight) > 75 Kg.

The detailed description of the inclusion and exclusion criteria of the subjects involved in the study is reported in the previous original study [15].

Smoking habits were investigated. All patients in this subgroup evaluated had never smoked or had stopped smoking for 5 years.

Subjects were randomized to one of the two arms (intervention or placebo) according to a pattern that ensures balanced treatment assignment (in a 1:1 ratio). Treatment consisted of 90 days of L112 or placebo tablets (2 × 2) taken before main meals, along with individual counseling to ensure adherence to the prescribed diet (written instructions were provided).

The primary endpoint was body weight (BW) modification, while secondary endpoints included changes in lipid profile, glucose levels, insulin resistance, body composition, blood pressure, plasma levels of vitamins (A, E, D3, K1), and oxidative stress markers (d-ROMs test and TRAP).

The detailed description of the methods used to evaluate the biochemical and anthropometric parameters is present in the previous original study study [15]. Oxidative stress was determined by measuring the levels of derivatives-reactive oxygen metabolites (d-ROMs) using photometric assay (Diacron srl, Grosseto, Italy) [18] and antioxidant reserve by measuring the total peroxyl radical-trapping antioxidant potential of plasma (TRAP) using a fluorometric assay. The values of TRAP are expressed as μmoles/L of peroxyl radicals trapped [19].

In this study, variables directly related to metabolic syndrome (MS) as defined by ATP III criteria were evaluated. Additionally, body composition, lipid profile, insulin resistance, and oxidative status (see Table 2), as well as BES (Binge Eating Scale) and BDI (Beck Depression Inventory) scores (see Table 1) were also considered.

Both groups were provided with individual counseling and written indications for the execution of a diet therapy in 3 balanced meals equal to 100% of the energy expenditure at baseline (EEB), evaluated by the Harris–Benedict equation, multiplied by the estimated activity factor, with 30% energy from lipids, 60% energy from carbohydrates, and 15% energy from proteins (with a minimum of 0.8 g of protein for the ideal correct weight), with a controlled sodium content and based on the Mediterranean food model.

Table 1 General characteristics of subjects in the subgroup of MS at baseline (T0) and relative treatments: frequencies or mean values ± sd

Variable	Measure	Treatment		ANOVA/χ^2
		Placebo	L112	*p*-Value
Male	N	3	5	ns
Female	N	9	9	ns
BES	Score	15 ± 9.5	13 ± 8.2	ns
BDI	Score	12 ± 7.8	11 ± 7.9	ns
Age	Years	54 ± 11.0	55 ± 12	ns
Education	1–2 [a]	0–12	2–12	ns
Physical activity	0-1-2 [b]	5-6-1	5-6-3	ns
Smoking	0-1-2 [c]	10-0-2	12-0- 2	ns

Legend; N = number; ns = not significant; BES = Binge Eating Scale; BDI = Beck depression inventory.

a = 1 secondary school; 2 university degree; b = 0 sedentary; 1 normal physical activity; 2 active physical activity; c = 0 never smoked; 1 no smoking for less than 5 years; 2 still smoking.

Statistical analysis

The ANOVA analysis split plot was used to determine the differences between treatments only according to PP (per protocol) values. The Partial Least Squares (PLS) Template was also considered in order to identify which variables have a greater impact on clinical responses as VIP (Variable Importance Plot) among treatment, age, smoking, binge eating scale, Beck depression inventory [20]. The SAS Institute's JMP14 Pro 2019 software was used for the analysis.

Results

A subgroup of 26 subjects (8 males and 18 females; age 55 ± 11.3 years; BMI 31.1 ± 1.35 kg/m²) with MS has been considered. The graphical abstract of the study is reported in Fig. 2. The characteristics and number of subjects with MS in the two subgroups are reported in

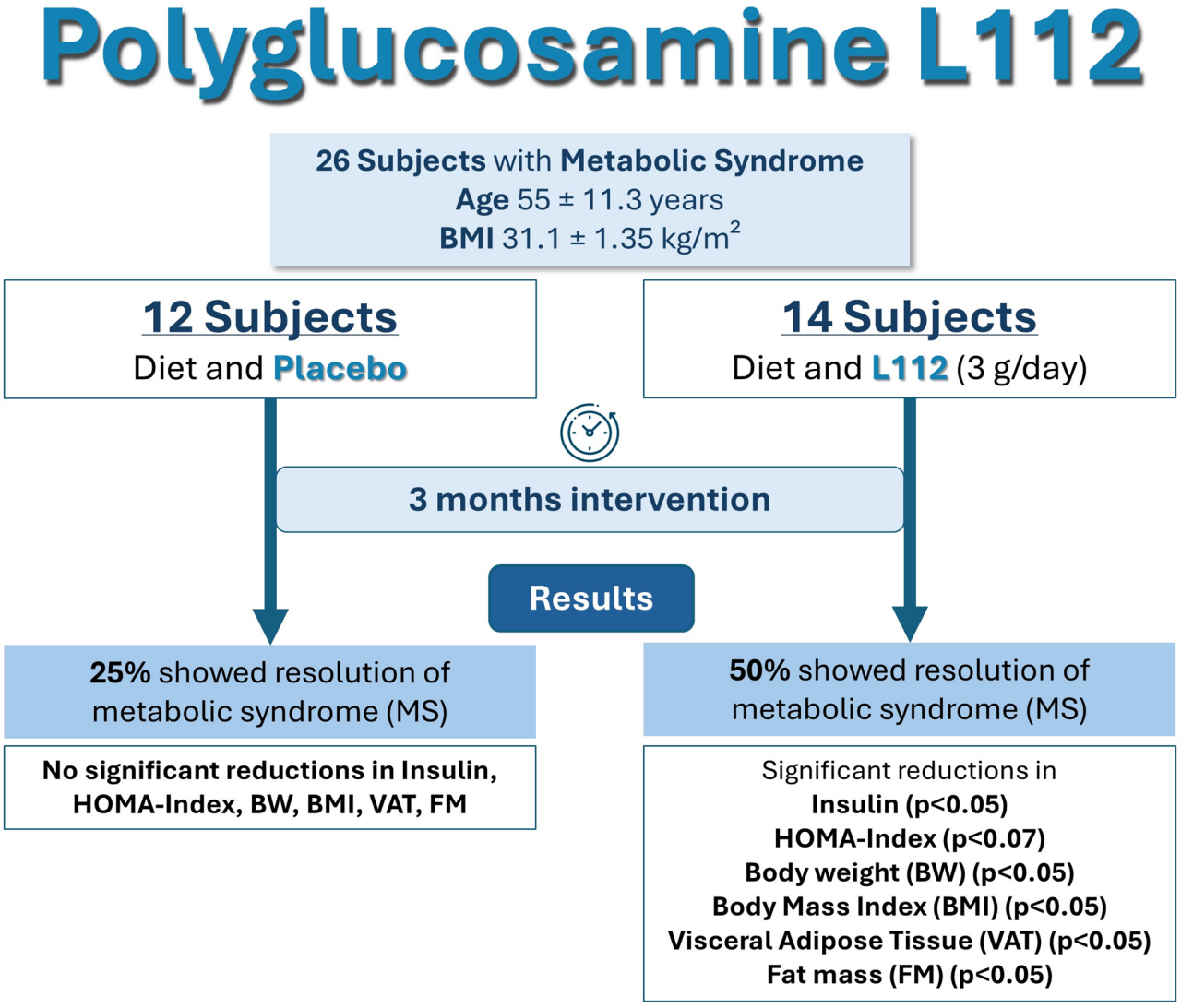

Fig. 2 Graphical abstract of the study

Table 1 with the relative variables. The volunteers were enrolled from May 2020 to 20 December 2021. There were no dropouts in this subgroup.

No significant difference was shown comparing the two subgroups at baseline. The main variables following the treatment with placebo of L112 are reported in Table 2.

After 3 months of treatment, the number of cases that resolved metabolic syndrome (MS) was 3 out of 12 (25%) in the placebo group and 7 out of 14 (50%) in the L112 group. The difference was statistically significant (Fisher $\chi^{2;}$ $p < 0.01$).

None of the typical MS variables were significantly altered due to the high variances of the two groups. In contrast, the anthropometric variables (i.e. BW, BMI), those related to fat mass (VAT, FM), and insulin resistance were significantly reduced by treatment with L112.

Safety variables such as AST, ALT, GGT, and creatinine were not modified in any of the subgroups, nor were the glucosamine plasma levels and vitamins (A, E, D_3, K_1) and data were nor reported. Figure 3 shows the VIP (Variable Importance Plot) for each predictive variable X in the PLS model, indicating that treatment is determinant for protection, while smoking, BES, and BECK may have lower importance; age, on the other hand, seems not to have influence. The model explained about 76% of the variance in the X variables, indicating that most of the information in the predictive variables was captured.

The treatment shows the highest value (1.69), indicating that it is the most important variable compared to smoking (0.98), BES and BECK (respectively 0.79 and 0.68), and age with the lowest value (0.29).

Table 2 Variables directly or indirectly bound to the MS in subjects treated with L112 or placebo: mean ± sd at baseline (T0) and after 3 months (T2)

Variable	Measure	Treatments				ANOVA
		Placebo [12 cases]		L112 [14 cases]		
		Baseline (T0)	3 Months (T2)	Baseline (T0)	3 Months (T2)	
TC	mg/dL	203 ± 49.1	198 ± 37.1	193 ± 39.8	183 ± 33.2	Ns
VLDL	mg/dL	35 ± 15.9	34 ± 18.8	29 ± 8.7	25 ± 9.6	Ns
LDL	mg/dL	127 ± 36.8	124 ± 31.3	120 ± 34.7	113 ± 29.70	Ns
HDL	mg/dL	43 ± 6.0	44 ± 7.2	44 ± 6.7	46 ± 13.3	Ns
TG	mg/dL	175 ± 79.4	168 ± 94.0	147 ± 43.5	126 ± 48.1	Ns
Glucose	mg/dL	98 ± 13.6	98 ± 14.3	109 ± 18.0	104 ± 17.2	Ns
Ins	mcU/mL	18.5 ± 11.31	18.9 ± 13.05	19.3 ± 9.15	13.9 ± 6.12	$P < 0.05$
HOMA	Ratio	4.7 ± 3.21	4.8 ± 3.81	5.2 ± 2.56	3.7 ± 1.85	$P < 0.07$
BW	Kg	89.5 ± 11.16	87.5 ± 10.95	90.2 ± 15.28	85.7 ± 14.14	$P < 0.05$
BMI	Kg/m^2	31.3 ± 1.18	30.5 ± 1.24	31.3 ± 1.44	29.6 ± 1.73	$P < 0.05$
AC	Cm	110 ± 8.9	106 ± 9.0	110 ± 12.0	105 ± 12.3	Ns
SBP	mmHg	128 ± 8.6	127 ± 10.1	128 ± 14.5	125.0 ± 12.7	Ns
DBP	mmHg	80.8 ± 4.17	82.5 ± 5.004	77.9 ± 10.32	79.3 ± 10.35	Ns
VAT	G	1512 ± 498.1	1456 ± 454.8	1727 ± 762.1	1429 ± 606.2	$P < 0.05$
FM	G	38,574 ± 7930.1	36,685 ± 8034.3	39,746 ± 10544.0	36,360 ± 9801.8	$P < 0.05$
LM	G	48,695 ± 8123.5	48,036 ± 8152.8	47,150 ± 7361.3	46,453 ± 7933.0	Ns
d-ROMs	mg H_2O_2/dL	34.4 ± 6.05	35.5 ± 7.08	36.6 ± 8.69	36.1 ± 9.59	Ns
TRAP	µMol	339 ± 16.0	346 ± 17.4	351 ± 16.8	347 ± 14.7	Ns

Legend: TC = total cholesterol; VLDL = very-low density lipoproteins; LDL = low-density lipoproteins.

HDL = high-density lipoproteins: TG = triglycerides; Ins = insulin; HOMA = homeostasis model assessment.

BW = body weight; BMI = body mass index; AC = abdominal circumference; SBP = systolic blood pressure.

DBP = diastolic blood pressure; VAT = visceral abdominal tissue; FM = fat mass; LM = lean mass: d-ROMs = reactive oxygen metabolites; TRAP = Total peroxyl radical-trapping antioxidant potential; Ns = not statistically significant.

Discussion

The present study demonstrates the efficacy of a three-month administration of L112 on resolution of MS: in the placebo group, 3 out of 12 cases (25%) showed resolution of MS, whereas in the L112 group, 7 out of 14 cases (50%) showed resolution. Differences were statistically significant. L112 was more effective than placebo on the reduction of BMI, BW, insulin resistance, VAT and FM, measured by DXA.

The changes in the mean values of the classic variables that define MS were not statistically significant. However, the majority of anthropometric measures (BW, BMI), the amount of body fat (VAT, FM), and insulin resistance were significantly reduced. This is most likely due to the short treatment. A long-term therapy with good chances would allow for a better highlighting of the activity of L112 as a single therapy.

According to ATP III, the combinations of 3 out of 5 variables allow for 10 different scenarios, and the normalization of even a single variable allows for the "exit" from the MS [1]. In this context, the greater effectiveness of L112, in cases responsive to therapy, has been observed in the reduction of TG and the increase of HDL. All of this seems to indicate a reduction in the bioavailability of lipids, confirmed by the significant reduction of insulin resistance and the protection of HDL from oxidative stress. The effect on the reduction of dietary lipid availability due to L112's fat-binding activity in the gut [21]. The reduction in insulin levels, which is known to be independent of body weight (BW) changes, suggests that L112 may contribute to the prevention of diseases associated with insulin resistance [22]. Notably, these results were achieved with just three months of treatment in the L112 group.

Oxidative stress (measured via the d-ROMs test) and antioxidant levels (measured via TRAP) showed only slight modifications, suggesting that the MS condition was in its early stages [23]. This observation is further supported by the absence of associated therapies in both subgroups.

Previous research has highlighted that the duration of treatment with L112 is the most critical factor in determining its effects on both BW and cholesterol levels (CH) [24].

The concomitant impact on multiple variables, such as body weight (BW), insulin resistance, visceral adipose tissue (VAT), and fat mass (FM), appears to enable L112 to reduce MS in a relatively short period.

The main limitations of this study are the small sample size and the short treatment duration, which are common when subgroups are analyzed. Long-term treatment should be considered to effectively address MS and to

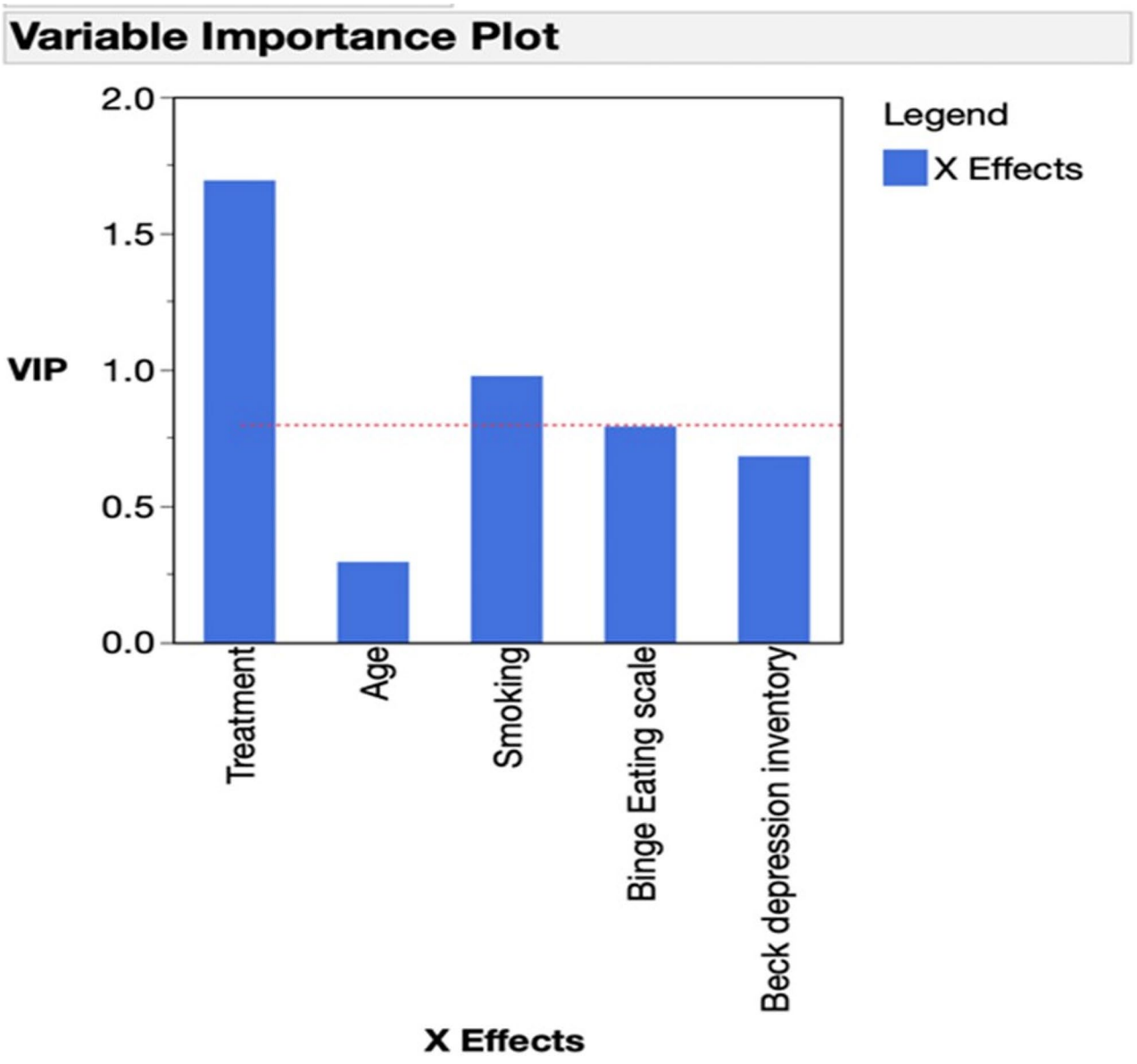

Fig. 3 Variables Importance in Protection for MS. Legend: in the model, the maximum of the variable effect is equal to 2: X corresponds to the variables

more precisely identify responders. This is feasible given the well-documented safety and tolerability of L112 [21, 25].

Conclusions

This is the first study conducted in order to evaluate the efficacy of polyglucosamine L112 on body weight, insulin resistance, and cholesterol in patients with metabolic syndrome. The studies conducted to date have considered only the efficacy of chitosans on MS and were limited to blood glucose. Polyglucosamine L112 instead consists of standardized polymers characterized by > 80% degree of deacetylation and a peak molecular weight (Mp) of about 65 KDa and was shown active on body weight, cholesterol levels and insulin resistance. This study demonstrated that the subgroup of patients suffering from MS and treated with L112 showed a significant improvement in 50% of the subjects despite the product being the only treatment administered for MS.

Due to the limited number of cases and the short period of treatment, no significant changes were observed in the average values of the typical MS variables. However, the anthropometric variables (BW, BMI), those related to body mass (VAT, FM), and insulin resistance were significantly reduced by L112. Long-term trials should be undertaken to confirm these results.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s40795-025-01153-8.

Supplementary Material 1

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Author contributions
Conceptualization, M.R. and B.C.; methodology, S.P.; formal analysis, S.P.;investigation, Z.P., M.N. and C.G.; data curation, M.D.P., F.L., E.P. and R.C.; writing—original draftpreparation, M.R., S.P. and C.G.; writing—review and editing, M.D.P., F.L., E.P. and R.C.; visualization, M.R., R.C. and B.C.; project administration, M.R. and B.C.; funding acquisition, M.R. All authors have read and agreed to the published version of the manuscript.

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Data availability
The data presented in this study are available on request from the corresponding author.

Declarations

Ethics approval and consent to participate
The study was conducted in accordance with the Declaration of Helsinki, and approved by the Bioethical Committee of the IRCCS San Matteo hospital, Pavia (protocol number: 15012020). Informed consent was obtained from all subjects involved in the study.

Consent for publication
Not Applicable.

Competing interests
The authors declare no competing interests.

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