

Mini Review

Volume 6 Issue 4 - March 2018
DOI: 10.19080/CRDOJ.2018.06.555691

Curre Res Diabetes & Obes J

Copyright © All rights are reserved by Umberto Cornelli

Body Weight Reduction with L112: Review of Double Blind Randomized Controlled Clinical Trials



Umberto Cornelli*

Loyola University School of Medicine, USA

Submission: March 06, 2018; **Published:** March 26, 2018

*Corresponding author: Umberto Cornelli, Dr SciHc Loyola University School of Medicine- Chicago, USA, Email: ucornelli@gmail.com

Introduction

The problems of body weight increase and obesity have a tremendous impact on the quality of life since they are associated with comorbidities and psychological problems. The latter is much more important than one may realize. People need to be satisfied with their appearance; getting a bit fat and experiencing increases in body weight and waist may alter their “self-esteem”.

Most of the time, the first approach to this problem is to reduce food intake, even though dieting is the hardest pill to swallow. Professionals in the field usually have to face the problems based on the recommendations of the triangle consisting of diet, physical activity and slimming products. No doubt that diet and exercise are efficient tools. However, there is many an argument constructed against weight loss products. Unfortunately, every day some new “miracle product” appears on the market, suggesting a fantastic body weight reduction. Academy is very concerned regarding all these products because they do not have a real scientific background, and most of the time, are based upon poor quality clinical trials. One of the most common products used in Europe to reduce body weight is the medical device formoline L112 (PG), which is a formulation containing polyglucosamine that is a derivative of chitosan.

The Cochrane database Systemic review has analyzed all the clinical trials done in the past (up to 2008) with chitosan [1]; the conclusion was that “There is some evidence that chitosan is more effective than placebo in short term treatment. However,

many trials to date have been of poor quality and results have been variable”. However, PG has two peculiar aspects:

- a) Chemico/physical characteristic;
- b) Its activity has been documented following Double Blind Randomized Controlled Clinical Trials conducted after 2015 [2-4] that are within the golden standard for the study of BW reduction.

From the chemico/physical point of view, PG is a polyglucosamine and consists of a polycationic polymer with a controlled molecular weight (MW). It is the only oral chitosan derivative belonging to Class III medical device. The MW is important for the activity on BW, since very large polymers tend to entangle once in contact with the body fluids, and lose part of their fat binding capacity. On the other side, polymers with very low molecular weight maintain the capability to reduce cholesterol levels (due to the biliary salt binding capacity), but are minimally effective on BW reduction. Polymers with MW between 150 to 350 KD such as PG, have been shown to be effective on BW provided that they are associated with appropriate organic acids; exactly as for PG. This is the reason why the MW of this derivative has to be controlled and kept identical in every production (batch stability). This is only possible, thanks to a very sophisticated technology that has been in place for about 15 years, introduced by the manufacturer of PG.

Table 1: Meta-analysis of 3 double blind placebo controlled randomized studies [2-4].

Product	N	Sex	Average Differences Baseline 3-Months			
			BW Kg	WC cm	BMI kg/m ²	5R ^a
PG L112	158	70 M/88 F	5.8 ^b	7.7 ^b	1.7 ^b	64%
Placebo	90	42 M/48 F	4.3	4.3	1.4	37%
% Difference between treatments						
In favor of PG			34.9	79.1	21.4	72.9

^a5R corresponds to the number of cases with a 5% body weight reduction

^bThe difference between the two groups is statistically significant (t test p< 0.01)

From the clinical point of view, according to the Cochrane suggestions, three different studies have been conducted in two European countries [2-4], followed by a meta-analysis to pool the data comparing PG with placebo. As in the case of this type of trial, the admission criteria were: a) overweight; b) BMI >30<35kg/m²; c) subjects free of any chronic diseases. The administered dosage was 2g/day (2 X 2 500 mg tabs) to be taken before or during the main meals. The diet consisted of a reduction of the caloric intake of about 350-500kcal/day and the physical activity was increased between 3 to 7 MET/h/week. The results documented in 248 cases are reported in Table 1.

During the treatment, the incidence of side effects (temporary constipation) was identical for both treatments and controls and could be overcome by just increasing the water intake during the day. The activity of PG was found to be significantly more consistent than placebo in all the variables that have been considered (BW, WC, and BMI). The average BW reduction of about 6kg in 3 months was an important achievement. The more consistent decrease of WC (7.7 vs 4.3cm) represents a 79 % higher efficacy than using placebo and represents the variable most affected by PG.

The reason of this very favorable effect is the capacity of PG to bind lipids [5] and decrease the omental fat mass. This is an important characteristic, since the omental fat is one of the causes of the inflammatory processes that are known to facilitate the tendency towards type II diabetes and cardiovascular diseases. This mechanism of the reduction of fat absorption was also determined experimentally, using the labelled oleic acid as marker [6]. It was clearly shown that oleic acid absorption was reduced by the administration of PG. Even more interesting was the evidence that most of the bound fats not eliminated with the feces, avoiding the phenomenon of steatorrhea which is known to be unpleasant. In fact, fats bound by PG are taken up by the colonic bacteria that use them as a fuel [7].

In terms of the achievement of the 5% reduction of BW (5R), PG showed more consistent results than placebo (about 73% more effective than placebo). This improvement is the answer to the psychological problem of self-esteem, indicating that

the goal to have an attractive physical appearance is not only a dream but can be achieved.

Conclusion

PG added to the diet was shown to be significantly more effective than placebo in treating overweight and obesity.

Acknowledgement

The clinical trials on formoline L112 (PG) were funded by Certmedica International GmbH, Ashaffenburg Germany.

Conflict of interest

The author declare that there is no conflict of interest. The founding sponsor played no role in the design of the studies, in the collection, analyses, or interpretation of the data, in the writing of the manuscript, and in the decision to publish the results.

References

1. Jull AB, NiMhurchu C, Bennet DA, Dunshea Mooij CA, Rodgers A (2008) Chitosan for overweight or obesity. *Cochrane database Syst Rev* (3): CD003982.
2. Pokhis MK, Bitterlich N, Cornelli U, Cassano G (2015) Efficacy of polyglucosamine for weight loss-confirmed in a randomized double-blind, placebo-controlled clinical investigation. *BMC Obesity* 2: 25.
3. Stoll M, Bitterlich N, Cornelli U (2017) Randomized, double-blind, clinical investigation to compare orlistat 60 mg and a customized polyglucosamine, two treatment methods for the management of overweight and obesity. *BMC Obes* 4: 4.
4. Cornelli U, Belcaro G, Recchia M, D'Orazio N (2017) Long term treatment of overweight and obesity with polyglucosamine (PG L112) randomized study versus placebo in subjects following caloric restriction. *Nutritional Journal* 1: e000919.
5. Dimzon IK, Ebert J, Knepper TP (2013) The interaction of chitosan and olive oil: effects of degree of deacetylation and degree of polymerization. *Carbohydr Polym* 92(1): 564-570.
6. Cnubben NHP, Tel SL, Hemmes MA, Langenkamp Brand A, Grossouw D, et al. (2016) A single oral dose of polyglucosamine influences the bioavailability of [9-(14)C-oleic acid in adult female Göttingenminipigs. *BMC Obes* 3: 18.
7. Bondiolotti G, Cornelli U, Strabbioli S, Frega NG, Cornelli M, et al. (2011) Effect of a polyglucosamine on the body weight of male rats: mechanism of action. *Food Chem* 124(3): 978-982.



This work is licensed under Creative Commons Attribution 4.0 License
DOI: [10.19080/CRDOJ.2018.06.555691](https://doi.org/10.19080/CRDOJ.2018.06.555691)

Your next submission with Juniper Publishers will reach you the below assets

- Quality Editorial service
- Swift Peer Review
- Reprints availability
- E-prints Service
- Manuscript Podcast for convenient understanding
- Global attainment for your research
- Manuscript accessibility in different formats
(Pdf, E-pub, Full Text, Audio)
- Unceasing customer service

Track the below URL for one-step submission

<https://juniperpublishers.com/online-submission.php>