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Basic nutritional investigation

Could dyslipidemic children benefit from glucomannan intake?

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ABSTRACT

Objective: Primary dyslipidemias are major risk factors for cardiovascular disease and should be addressed early in life. The aim of this study was to evaluate, in children affected by primary hypercholesterolemia, the efficacy and tolerability of a short-term treatment with a dietary supplement containing glucomannan.

Methods: A double-blind, randomized, placebo-controlled, cross-over trial was conducted in 36 children (aged 6-15 years) affected by primary hypercholesterolemia. After a 4-week run-in period with dietary counseling, children received glucomannan or placebo twice-daily for 8 weeks, separated by a 4-week washout period. Lipid profile was assessed at baseline and after each treatment period.

Results: Glucomannan significantly reduced total cholesterol (TC) by 5.1% ($p = 0.008$), low-density lipoprotein cholesterol (LDL-C) levels by 7.3% ($p = 0.008$) and non-high-density lipoprotein cholesterol by 7.2% ($p = 0.002$) as compared with placebo. No significant differences were observed in high-density lipoprotein cholesterol, triglyceride, Apolipoprotein B, and Apolipoprotein A-I concentrations. According to sex, glucomannan significantly reduced in females, but not in males, TC (-6.1%, $p = 0.011$) and LDL cholesterol (-9%, $p = 0.015$). No major adverse effects were recorded and only few patients experienced transitory intestinal discomfort.

Conclusion: Treatment with glucomannan of children affected by primary dyslipidemia is well-tolerated and effectively lowers total and LDL cholesterol in females and non-high-density lipoprotein cholesterol, but not Apolipoprotein B in both males and females.

Introduction

Primary dyslipidemias are major risk factors for cardiovascular disease (CVD) [1]. The associated lipoprotein changes start early during childhood and remain throughout adulthood [2]; indeed, atherosclerotic lesions have been recorded in pediatric patients [3]. Therefore, increased attention is being paid to CVD prevention in childhood, through lipid-lowering strategies when applicable. The main approaches focus on lifestyle changes that chiefly concern diet and physical activity. When these approaches do not lead to a satisfactory reduction of low-density lipoprotein cholesterol (LDL-C) concentrations, the use of dietary supplements/functional foods is warranted, before prescription of hypolipidemic drugs [2].

Soluble fibers bind biliary salts and remove them from the enterohepatic circulation, thus representing an interesting example of dietary supplement aimed at cardiovascular prevention [4]. Several studies have focused on different soluble fibers such as glucomannan, oats, psyllium, pectin, and guar gum. Glucomannan, the main polysaccharide obtained from the tuber *Amorphophallus Konjac* (a member of the Araceae family, found in East Asia) is a palatable soluble fiber. In the East, people have being consuming glucomannan for thousands of years; its use also is increasing in the West. The chemical structure of glucomannan consists in a mannose:glucose 8:5 ratio, linked by β-glycosidic bonds. Glucomannan has the highest molecular weight and viscosity of any other known dietary fibers [5] and, like other soluble fibers, has been tested for its potential beneficial effects on risk for CVD, in particular because of its favorable effects on lipid profile [6].

Clinical trials have been carried out in adults to investigate the effects of fiber on body weight, blood pressure, fasting blood glucose, and lipid profile, yielding mixed results [7]. A meta-analysis of the efficacy of glucomannan in lowering LDL-C

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reported great variability among 14 studies conducted in adults and children [6]. More recently, inverse correlations between dietary [total, soluble, and insoluble] fiber intake and C-reactive protein, a sensitive marker of inflammation, were reported in healthy [8] and dyslipidemic [9] adults. In children, studies that evaluated the effect of water-soluble fibers on lipid profile show LDL-C reductions ranging from null to 30% [10–20]. Again, there is no concordance among the results of various trials [4,6].

This study had two main objectives: 1) to confirm the effects of glucomannan in lowering LDL-C in boys and girls and 2) to evaluate whether this dietary intervention modifies apolipoprotein B (ApoB).

Materials and methods

Patients

The study complies with the Declaration of Helsinki and was approved by the Local Ethics Committee. Written informed consent was obtained from patients and their legal guardians.

We recruited 36 hypercholesterolemic children among 42 outpatients followed by our Lipid Clinic since October 2011, who were screened for eligibility. Enrollment criteria included being ages 6 to 15 y with serum total cholesterol (TC) levels higher than their age- and sex-specific 90th percentile. Exclusion criteria comprised secondary dyslipidemias, overweight or obesity (body mass index [BMI] $\geq$ 85th and $\geq$ 95th percentile, age and sex matched, respectively), renal, endocrine, liver disorders, or chronic diseases requiring drug treatment (i.e., immunologic, neurologic, or oncohematologic disorders). Diagnostic criteria were based on accepted International standards [21]. As with familial hypercholesterolemia (FH) (n = 5), criteria included children with LDL-C $\geq$ 135 mg/dL, parental hypercholesterolemia with LDL-C $\geq$ 190 mg/dL, tendon xanthomas and/or CVD (phenotype IIA). Children showing TC and/or triglyceride (TG) above the 90th age- and sex-specific percentile, at least one parent affected by isolated hypercholesterolemia, hypertriglyceridemia, or both (IIA, IV, or IIB phenotype, respectively) with concomitant individual and familial lipid phenotype variability were diagnosed as familial combined hyperlipidemia affected (FCH) (n = 19). Children exhibiting LDL-C exceeding 90th percentile and a family history of hypercholesterolemia, but who did not fulfil the biochemical international criteria for inclusion in FH or FCH, were considered affected by undefined hypercholesterolemia (n = 12). All study participants were nonsmokers and no participants were on lipid-lowering treatment—including functional foods—for the 3 mo before the beginning of the study.

Study design

This double-blind, randomized, placebo-controlled, cross-over trial lasted 24 wk. Participants underwent four visits and were submitted three times to biochemical analyses (biochemical analyses were not performed at the start of the second half of the study). Moreover, food-intake evaluations were performed at baseline and at the end of each treatment (Fig. 1). This latter procedure was implemented to diminish the risk for attrition, which increases when children undergo frequent visits.

Children underwent a preliminary 4-wk run-in diet and were instructed by a trained dietitian not to change their standard low-saturated fat, low-cholesterol diet (i.e. the Step I diet) [22]. This first-level dietary approach consists of a normocaloric diet composed as follows: carbohydrate 55%, protein 15%, total and saturated fat 30% and 10%, of daily calories respectively. Cholesterol intake was less than 300 mg/d. Furthermore, children and their families were instructed not to modify children's physical activity. An external pediatrician randomly allocated the participants to receive either fiber or placebo. Randomly enrolled patients (N = 36) were assigned to consume either the dietary supplement or the placebo. Eighteen children started with the dietary supplement and 18 started with the placebo, for 8 wk each. At the end of the first treatment period, children underwent

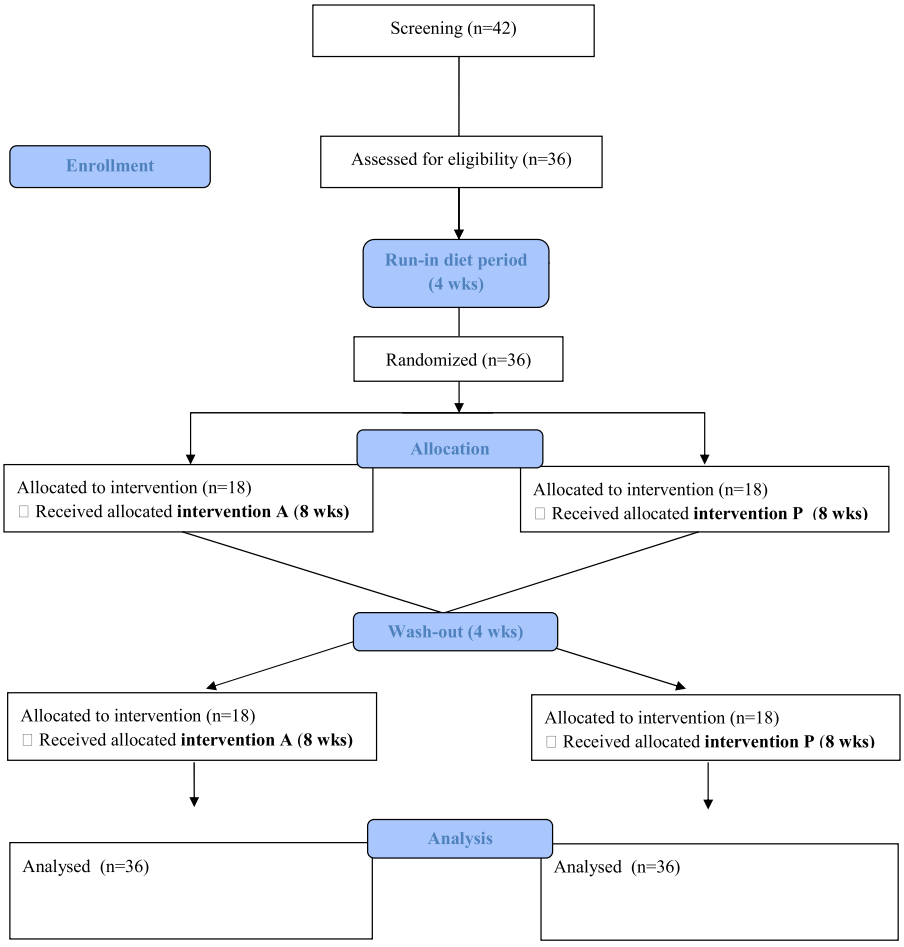

Fig. 1. Flowchart of the study. Intervention A: glucomannan; Intervention P: placebo.