FRUIT UP®, THE ALTERNATIVE NATURAL SWEETENER FROM CAROB (*CERATONIA SILIQUA*) WITH FUNCTIONAL EFFECTS ON GLUCOSE METABOLISM

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Introduction

The carob tree (*Ceratonia siliqua*) belongs to *Fabaceae* family, widely cultivated in the Mediterranean arch since historical times. Nowadays Spain is the main worldwide producer. The carob pod does contain several compounds, and among them, Sugars represent the highest concentration rate. Considering their bioactive compounds, Carob pods are highly rich in soluble and insoluble polyphenols (phenolic acids, flavanols, condensed tannins), inositols (i.e., pinitol, myo-inositol), soluble (i.e, arabinoxylans) and insoluble fiber (mainly lignin), minerals (K, Ca), and proteins.

FRUIT UP® is a new generation functional ingredient obtained by mechanical extraction of carob pods and physical refining. The core of the FRUIT UP® composition are the soluble carbohydrates (sugars, and inositols), together with the soluble fiber fraction as well. It is the first concentrated fine sweet syrup from Carob, enriched in inositols, with functional effects scientifically tested in more than 40 different human clinical trials already published in peer review journals. Its great sweet taste clearly provides the biggest application advantage.

Objective

Inositols, naturally occurring in FRUIT UP® are thought to be mediators of the insulin signalling pathway. We clinically studied, in Healthy Subjects, the effects of the regular and chronic intake (3 months) of FRUIT UP®, in beverage form (Inositols Enriched Beverage), on the improvement of the Glycaemic control (in fasting and postprandial states), also the Insulin levels and Insulin Resistance. Secondarily, the Lipid and Lipoprotein profile.

Methods

Human Clinical Study.

A 12-week double-blind RCT with N=40 healthy subjects administered either an Inositol-enriched beverage (IEB-FRUIT UP®), and containing 2,23 g of Inositols in 250 ml or a sucrose-sweetened beverage SSB (placebo), matching Total Available Carbohydrates, both twice a day per subject (2 x 250 ml drinks per day, 2 hours BEFORE Lunch & Dinner, at 11:00 h & 19:00 h), based on the results of previous Dose-Response-Bioavailability Human-Clinical Trial of FRUIT UP® (publication available).

Anthropometric measurements, fasting glucose levels, insulin and HOMA-IR index, lipoprotein profile and postprandial glucose concentrations (measure using the continuous glucose monitoring system-CGMS were recorded throughout the intervention period (every 24 h a 3-day period at 0-2 weeks and 10-12 weeks of the study).

Results

Following the 12-week trial with intake of FRUIT UP®, the healthy subjects exhibited, respect the Placebo group (sucrose):

+ Post-Prandial Glycaemic Response (PPGR): approx. 14 % of mean reduction of glucose. p< 0.05 (see Figures)
+ Percentage of Mean Glucose change: net reduction of min. 12. 7 – max. 15.14 %. p<0.05
+ Fasting Insulinaemia Response: approx. 11 % reduction. p< 0.033
+ HOMA-IR Index (Fasting): approx. 10 % reduction. p< 0.05
+ Percentage of the AUC change in Blood Glucose profile of 72 hours: approx. 10 % reduction. p<0.007
+ Significant decrease in Apo B (- 6.9 %) in fasting conditions.

Table 1. Lipoprotein profile and carbohydrate metabolism parameters of healthy subjects at baseline and after 6 and 12 weeks following a normocaloric diet plus sucrose-sweetened beverage (SB) or inositol-enriched beverage (IEB).

	Group	Baseline	6 Weeks	12 Weeks	Main effects (p value)		P interaction
					P time	P treatment	
Glucose (mg/dl)	SB	86.0 ± 6.0	89.0 ± 6.2*	87.9 ± 7.6	0.688	0.367	0.015
	IEB	89.9 ± 8.9	86.5 ± 8.0	89.8 ± 9.1			
Insulin (µIU/ml)	SB	6.76 ± 2.46	7.31 ±2.16	7.48 ± 2.31	0.410	0.805	0.033
	IEB	7.35 ± 2.20	5.90 ±1.75*	6.61 ± 1.96*			
HOMA-IR index	SB	1.43 ± 0.51	1.61 ± 0.49	1.61 ± 0.47	0.364	0.610	0.005
	IEB	1.65 ± 0.57	1.27 ± 0.40 *a	1.45 ± 0.42*#			
Apo B (mg/dl)	SB	90.5 ± 28.6	90.0 ± 23.9	86.7 ± 20.0	0.025	0.796	0.218
	IEB	93.0 ± 22.9	83.3 ± 17.2	80.7 ± 18.6*			
LDL particle size (nm)	SB	27.08 ± 0.29	-	27.04 ± 0.26	0.228	0.333	0.022
	IEB	26.91 ± 0.30	-	27.04 ± 0.35*			

Data are expressed as mean ± SD for parametric data or as median (25th and 75th percentiles) for non-parametric data. Between-group (treatment) and within-group differences (time) were analysed using two-factor repeated-measures analysis of variance (ANOVA). * p < 0.05 when compared with baseline, # p < 0.05 when compared with 6 weeks by means of one way repeated-measures ANOVA or Friedman test for parametric and non-parametric data, respectively, followed by a post hoc test. Superscript letters (a) indicate significant differences (p < 0.05) between groups (SB and IEB) when compared by an unpaired Student's t-test at specific time points. The Chi-Square test was used to compare proportions among groups.

Results of continuous glucose monitoring of a healthy population 2h after breakfast (Fig. 1) , lunch (Fig 2.), dinner (Fig 3.) following chronic consumption of sucrose-sweetened beverage (SB) or an inositol-enriched beverage (IEB).

A. Glucose levels in subjects receiving SB measured every five minutes at the beginning (red line) and at the end of the experimental period (soft red line).
B. Glucose levels in subjects receiving the IEB measured every five minutes at the beginning (blue line) and at the end of the experimental period (soft blue line).
C. Percentage of glucose change in SB (red line) and IEB (blue line) groups.
D. Mean of glucose change as a percentage in subjects consuming SB (red bar) or IEB (blue bar). Data are represented as mean ± standard error of 10 subjects in each group. Statistical significance (p < 0.05) was considered when compared by a paired Student's t-test in panels A and B and when compared by an unpaired Student's t-test in panels C and D.

Fig.1.

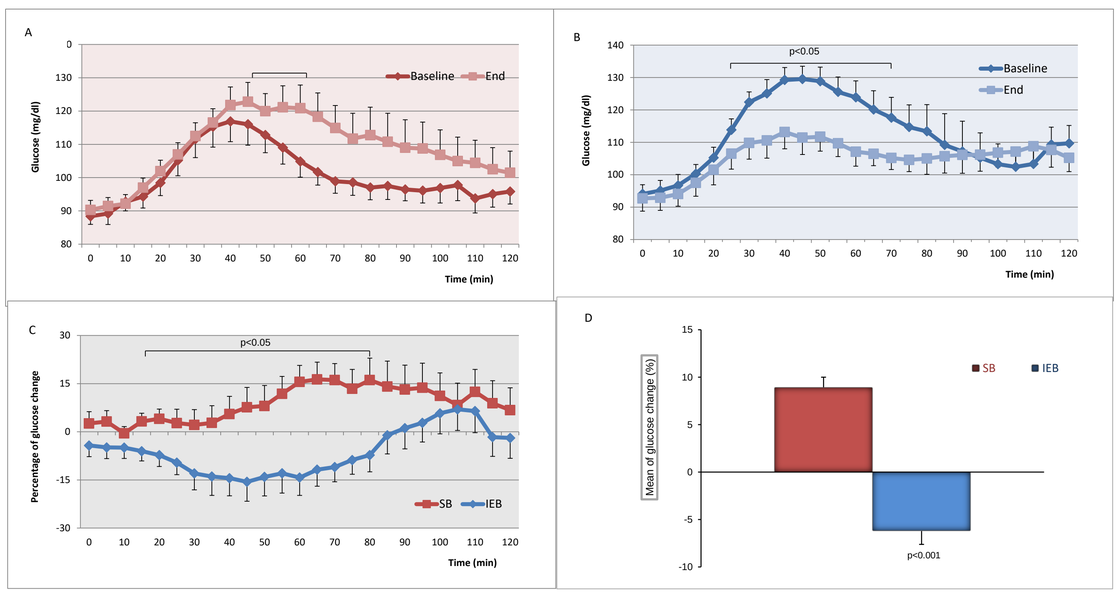


Fig.2.

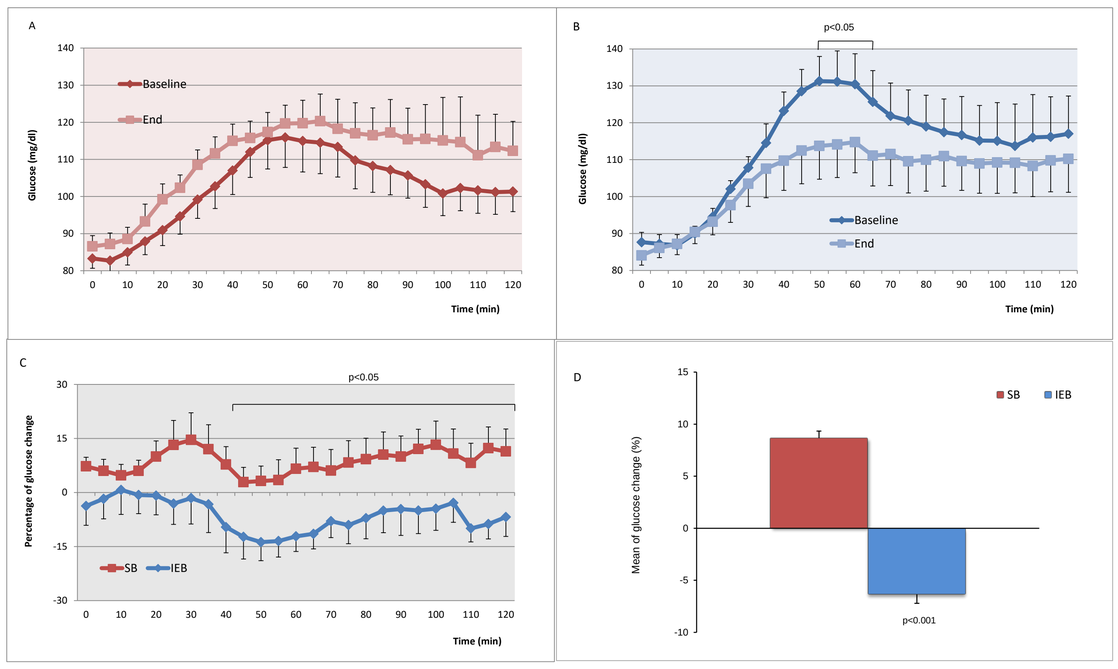
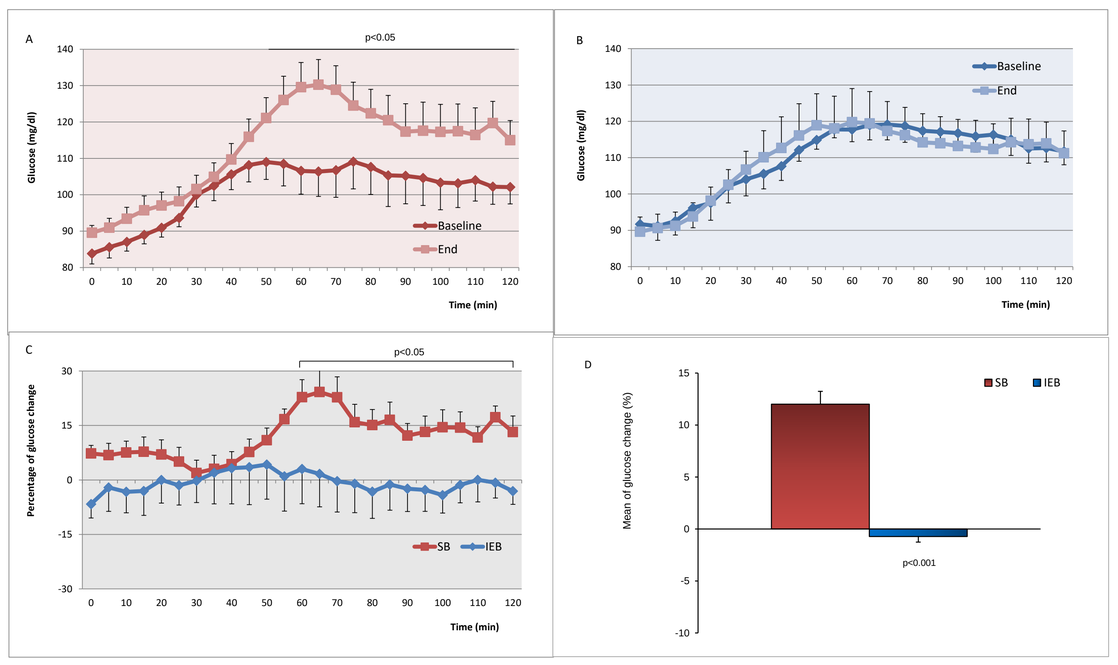


Fig.3.



Conclusions

Our results suggest that the chronic supplementation and/or replacement of a common sugar source, such as sucrose, by a naturally-based inositol enriched FRUIT UP® food or beverage induces a significant improvement in the Carbohydrates metabolism and their Glycaemic-Insulinaemic parameters, in Healthy subjects. All those biomarkers are critical for the delay of the onset on the Pre- and Diabetes Type 2 (prevention effect). The role of Inositols, naturally occurring in FRUIT UP®, is crucial to understand the biological plausibility of its health beneficial effects.

These results have been also complemented by additional human-clinical studies of FRUIT UP® in Pre-Diabetics (IFG; N=44) and Diabetics Type 2 individuals (N=38), also published in peer review journals. Those results clearly show significant improvement of the relevant biomarkers directly associated at those disease status, strengthening the conclusions about the significant role of FRUIT UP® within the control and modulation of the Glycaemia & Insulinaemia.

Remarks

Finally, more than 30 Glycaemic-Insulinaemic Index (GI-PPGR/II-PPIR) human clinical trials have been achieved on FRUIT UP® vs Glucose, according ISO 26642, with N=10 (healthy subjects per trial): all the results have shown a LOW GI (41-42) and LOW II (37-38).

One additional FRUIT UP® acute intake-clinical study with N=36 (healthy subjects) vs sucrose has also shown a very significant reduction (PPGR: - 19 %; PPIR: - 21 %).

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References: Bañuls Celia et. al Clinical Nutrition 35 (2016), pages 600-607

Conflict of interest statement: Rafael Salom works at ADM. rafael.salom@adm.com

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