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Research report

Dose–response effect of a novel functional fibre, PolyGlycopleX[®], PGX[®], on satiety [☆]Vicky A. Solah ^{a,*}, Jennie C. Brand–Miller ^b, Fiona S. Atkinson ^b, Roland J. Gahler ^c,
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ABSTRACT

The objective of this research was to determine the dose–response effects of a palatable, viscous and gel forming fibre, PolyGlycopleX[®] (PGX[®]), [(α -D-glucurono- α -manno- β -D-manno- β -D-gluco), (α -Lgulurono- β -D mannurono), (β -D-gluco- β -D-mannan)] on satiety, and to gain insight into the underlying mechanisms that lead to appetite inhibition. Healthy subjects ($n = 10$), aged between 20.3 and 29.2 years, consumed PGX[®], in granular form at 2.5, 5.0 and 7.5 g, and a 5g inulin control, with a standard breakfast. The PGX[®] doses of 2.5 and 7.5 g mixed with water at the start of breakfast increased satiety (iAUC of 140.0 and 157.7, $P = 0.025$ and 0.001, respectively) compared to the control. The most effective dose (7.5g) was palatable and corresponded to a 34% increase in fullness, measured using a visual analogue scale and incremental area under the curve, and resulted in a delayed postprandial glycaemic response when compared with the control.

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Introduction

Satiety is defined as the sensation of fullness as a consequence of eating that inhibits the resumption of eating (Gerstein, Woodward-Lopez, Evans, Kelsey, & Drewnowski, 2004). Dietary and functional fibre include naturally occurring edible and synthetic carbohydrate polymers, non-starch polysaccharides including hydrocolloids (i.e. gums, mucilage, β -glucan), resistant oligosaccharides, and resistant starch, and have a physiological effect that is of benefit to health (Codex Alimentarius Commission, 2011; Phillips, 2011; Slavin, 2003). The consumption of food with a high fibre content has been linked to enhanced satiety and may result in reduced energy intake, and

therefore plays a key role in weight regulation and the reduced risk of disease (Burton-Freeman, 2000; Hull, Re, Tiihonen, Viscione, & Wickham, 2012; Marciani et al., 2001; Paxman, Richardson, Dettmar, & Corfe, 2008; Pelkman, Navia, Miller, & Pohle, 2007; Pereira & Ludwig, 2001; Slavin & Green, 2007; Slavin, 2005).

The physical form of fibre and viscosity has been shown to provide higher satiety than nutrients, such as protein, alone (Hogenkamp, Mars, Stafleu, & de Graaf, 2012; Marciani et al., 2001; Solah et al., 2010). Food containing viscous fibre has a beneficial satiety effect beyond that of non-viscous fibre, and low-glycaemic foods are more satiating compared to high-glycaemic foods (Holt & Brand-Miller, 1994; Holt, Brand-Miller, & Stitt, 2001). Vuksan et al. (2009) found that high viscosity PolyGlycopleX[®] (PGX[®]), [(α -D-glucurono- α -manno- β -D-manno- β -D-gluco), (α -Lgulurono- β -D mannurono), (β -D-gluco- β -D-mannan)] reduced hunger and ad libitum food consumption when compared to low-viscosity cellulose and medium-viscosity glucomannan, and when given as meal replacement drinks. Different viscous fibre types vary in the degree of viscosity, and this increased viscosity, as well as subsequent gel formation of some fibres, may also result in nutrients being bound for longer periods of time (Brand-Miller et al., 2010, 2012; Kristensen & Jensen, 2011; Mars, Stafleu, & de Graaf, 2012; Mattes, 2007; Reimer et al., 2010). Binding of nutrients may slow the release of glucose

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into the blood, affecting appetite-regulating peptides such as peptide YY (PYY) and glucagon-like peptide-1 (GLP-1) (Grover et al., 2011).

Researchers have reported a dose response of different fibre types on satiety. In a 3-week, double blind, placebo controlled, crossover trial on 45 women, Kacinik et al. (2011) showed that adding PGX[®] to meals during consumption of a low-calorie diet reduced subjective ratings of prospective consumption and increased feelings of satiety, when compared to the addition of a low viscosity placebo. Similarly, an inverse dose–response effect of sodium alginate, an algal gelling polysaccharide containing guluronic acid and mannuronic acid units, on ad libitum food intake was found by Wanders et al. (2013). Higher doses of a non-viscous dextrin, NUTRIOSE[®], increased satiety (Guérin-Deremaux et al., 2011). In contrast Van Nieuwenhoven, Kovacs, Brummer, Westerterp-Plantenga, and Brouns (2001) found no effect of different doses of guar gum on gastric emptying.

There are numerous and complex interactions in digestion, especially in a mixed meal, that complicate the issue of satiety (Blackwood, Salter, Dettmar, & Chaplin, 2000; De Graaf, Blom, Smeets, Stafleu, & Hendriks, 2004; Wanders et al., 2011). The satiety mechanisms involving the consumption of dietary or functional fibre may involve a specific blood glucose level effect on satiety and other stimuli effects such as that of peptides including cholecystokinin (CCK), that are involved in the control of appetite (Borner, Jardy-Gennetier, Jacquet, & Stowell, 2007). Viscous dietary fibre can slow down gastric emptying and concurrently increase stomach distension (Hoad et al., 2009). Fullness may cause or influence the chain of events that lead to satiation (De Graaf et al., 2004; Ritter, 2004), and the physical and physicochemical properties of foods result in various signals, which can contribute to satiation (Benelam, 2009; Cummings & Overduin, 2007; Ritter, 2004). Viscosity influences gastrointestinal hormonal responses (Juvonen et al., 2009; Odunsi et al., 2010), and gastrointestinal hormone release influences satiety (Delzenne & Cani, 2005). The addition of dietary or functional fibre to food can decrease total energy intake and increase viscosity and water holding capacity of digesta and cause the formation of gels in the stomach (Blackwood et al., 2000; Hoad et al., 2004; Livesey, 1992; Poppitt & Prentice, 1996). The fibre and water relationship is an important aspect that must be considered in satiety studies.

Palatability, liking or pleasantness is increasingly measured in dietary intervention studies to ensure that any benefit offered in consuming the diet is matched by dietary acceptance (Hall, Baxter, Fryirs, & Johnson, 2010; Ibrügger, Kristensen, Mikkelsen, & Astrup, 2012). A product that is palatable, satiating and delays postprandial glycaemia is important in regulating food intake, and has important public health significance in the control of obesity.

PolyGlycopleX, PGX[®], is a commercial novel functional fibre complex (α -D-glucurono- α -manno- β -D-manno- β -D-glucosyl- α -L-gulurono- β -D-mannuronic acid), (β -D-glucosyl- β -D-mannan) (Inovobiologic Inc., Calgary, Canada) and is manufactured by a proprietary process (EnviroSimplex[®]) using three dietary fibres to form a highly viscous polysaccharide with high water holding and gel forming properties.

The aims were to measure feelings of fullness and hunger, over two hours, on a visual analogue scale of three doses of PGX[®] and a control, and to determine if a relationship with plasma glucose over the same two-hour time frame exists.

Methods

Study design

A single-blind, randomised controlled, crossover trial was conducted on 10 healthy subjects, aged between 20.3 and 29.2 years, selected from a pool of 16 pre-screened subjects. Subjects were recruited through the Sydney University Glycaemic Index Research

Service volunteer roster. Criteria for inclusion were body mass index <25 kg/m² and fasting blood glucose <5.5 mmol/L. Subjects taking medications or dietary supplements were excluded. The study was conducted at the University of Sydney and was approved by the Human Research Ethics Committee of the University of Sydney. Informed written consent was obtained from all subjects before the start of the study.

The study was an incomplete block design, with the three inulin controls (containing 5 g Orafit[®] inulin, sourced from Beneo, a low viscosity fibre) consumed at the beginning, middle and end of the study, and 2.5 g, 5 g and 7.5 g of PGX[®] fibre consumed in random order. All subjects fasted for 10–12 h overnight, then came to the test room on the same morning, but at different times between 6.30 and 8.30 a.m. and were randomly allocated to one of the test conditions. On arrival, subjects entered the test room where they were asked to sign the consent form. Subjects answered the question “what time was your last meal?” on the satiety questionnaire. All subjects participated in six 2-h test sessions, separated by a two- or three-day wash-out period, thus up to two tests per week.

Subjects were assigned a three digit number and randomised to one of the test conditions. Condition 1 was: inulin control on test day 1; 2.5 g PGX[®] on test day 2; inulin control on test day 3; 7.5 g PGX[®] on test day 4; inulin control on test day 5; and 5 g PGX[®] on test day 6. Condition 2 was: 5 g PGX[®] on the first test day; inulin control on test day 2; 2.5 g PGX[®] on test day 3; inulin control on test day 4; 7.5 g PGX[®] on test day 5; and inulin control on test day 6. Condition 3 was: inulin control on test day 1; 7.5 g PGX[®] on test day 2; inulin control on test day 3; 5 g PGX[®] on test day 4; inulin control on test day 5; and 2.5 g PGX[®] on test day 6. The PGX[®] for the additional conditions was randomised according to the block design. The inulin control and PGX[®] granules were consumed as part of a standard meal (which included Tip Top white bread, George Weston Foods, Sydney, NSW, Australia), which contained 50 g of available carbohydrate (defined as total carbohydrate minus dietary fibre). The inulin control and PGX[®] granules were dissolved in 2 × 250 ml glasses of water and consumed with the standard meal. Sufficient water was used to hydrate the product before consumption and eliminate the effects of its hydrophobic nature post consumption. The subjects consumed the test meal within 12 min (2 glasses of water containing PGX[®] within the first 5 min and bread within 12 min) and completed a 150 mm visual analogue scale (VAS) before the start of eating (time 0). After this, subjects remained in the testing room for 120 min to rate their appetite and provide finger prick blood samples at 15, 30, 45, 60, 90 and 120 min after the start of eating.

Palatability (liking)

Palatability was determined using a Likert scale to access “liking”. The question “How much did you like this food?” was rated on a 150 mm Likert scale, marked with 7 descriptors that ranged from “dislike very much” to “like very much”, where “dislike very much” = –3, “dislike moderately” = –2, “dislike slightly” = –1, “neither like nor dislike” = 0, “like slightly” = 1, “like moderately” = 2, and “like very much” = 3.

Dietary acceptance was assessed using the question, “How difficult was the food to eat?”, which was rated on a 100 mm VAS, anchored at both ends with 2 descriptors, “not difficult at all” which = 0 and “extremely difficult” which = 10.

Satiety measurement

The question “How hungry do you feel now?” was determined on a 150 mm VAS, where the scale was anchored at equally spaced intervals with words to describe the feeling of hunger from

“How hungry or full do you feel right now?”

extremely hungry hungry slightly hungry no particular feeling slightly full full extremely full

Fig. 1. Visual Analogue Scale (VAS).

“extremely hungry” to “extremely full”, as previously described by Holt, Brand-Miller, Petocz, and Farmakalidis (1995). The VAS was an unmarked 150 mm horizontal line and subjects placed a vertical line along the first 75 mm of the VAS to correspond with hunger or along the second 75 mm to correspond with fullness (Fig. 1).

The score on the VAS was measured for each subject from the centre point, so a maximum of 75 mm equated to “extremely full” and negative 75 mm to “extremely hungry”. The University of Sydney converts VAS results to a satiety score of 1 to 3 for satiety, where a score of slightly full is 25 mm on the VAS and is assigned a score of 1, 50 mm a score of 2 and 75 mm a score of 3. The results from each subject’s VAS were entered into Microsoft Excel. The incremental area under the curve (iAUC) was calculated for each subject ($n = 10$) using the trapezoidal method. The VAS at time 0 (fasting result) was subtracted from the subject’s fullness rating at each time measured (15–120 min), and the baseline was adjusted to 0. The iAUC was determined to show change in satiety from the baseline, so the fasting satiety level at the baseline was subtracted from subsequent values.

Plasma glucose measurement

The subjects fasted overnight for at least 10 h and arrived at the metabolic kitchen in the morning. Each subject was weighed, and two fasting blood samples were collected by finger-prick. The subject consumed the test meal within 12 min, and further blood samples were obtained at 15, 30, 45, 60, 90 and 120 min after the start of eating. Whole blood samples (0.7 mL) were collected from the fingertip into heparin-coated, micro-centrifuge tubes prior to consumption of the test meal (time 0) and at 15, 30, 45, 60, 90 and 120 minutes after eating commenced. Each blood sample was centrifuged for 45 s at 12 500×g. The plasma glucose concentration was analysed in duplicate using a glucose hexokinase enzymatic assay on an automatic spectrophotometric analyser (Roche Diagnostic Systems, Sydney, NSW, Australia).

Statistical analysis

The incremental area under the curve (iAUC) of test meals with PGX[®] at different dose levels from baseline to time 120 min was used as an outcome variable. The multilevel mixed-effects linear regression was used to assess the difference in iAUC between the control and the different doses (2.5 g, 5.0 g, 7.5 g). A mixed model was used to address the intraclass correlation, as each subject was tested 6 times. The test groups variable was entered into the model as a fixed effect, and the subjects’ ID was entered as the random effect, according to the structure of the panel data. The standard error was further adjusted using the vce (robust) option in the Stata program accounting for intragroup correlation. A regression model was used to determine the association between plasma glucose, PGX[®] dose and fullness. All analyses were

performed using Stata statistical software (SE 12.1, StataCorp, College Station, TX, USA).

Results

Palatability

The subject’s rating of “How much did you like this food?” ($n = 10$ and each subject conducted the test 3 times) resulted in a “neither like nor dislike/like slightly” rating, with a mean of 0.1 ± 1.0 and a median of 0. There was no significance difference in the rating for all test products, when consumed with the standard meal. Subjects found the test meal not difficult to eat, with a mean rating of 3 ± 2.0 .

Fullness rating

Fullness (iAUC) (calculated by mm times minutes and rating times minutes) and VAS fullness (rating) increased for all test products compared to the control (Table 1 and Fig. 2).

PGX[®] exhibited a significant impact on short-term satiety as measured by iAUC for fullness over time. The iAUC results show the control (0g PGX[®]) iAUC was significantly different from 2.5 g PGX[®] ($P = 0.025$) and 7.5 g PGX[®] ($P = 0.001$). The 2.5 g and 5 g iAUC were significantly different ($P = 0.0009$ and 0.0361 , respectively) from 7.5 g. There was no significant difference between iAUC fullness for the three controls, with iAUC values of 2214, 2256 and 2442 mm × min or 88.6, 90.2, 97.7 rating × min ($P = 0.105$ and $P = 0.587$).

The PGX[®] doses of 2.5 and 7.5 g, mixed with water at the start of breakfast, increased satiety (iAUC of 140.0 and 157.7, $P = 0.025$ and 0.001 , respectively) compared with the control. The PGX[®] dose of 5 g mixed with water at the start of breakfast increased satiety to the 60 min time point compared with the control. The lack of dose linearity may be due to within subject variability when rating fullness, past the 60 min time point. All subjects ($n = 10$) ranked PGX[®] at 7.5 g as providing greater VAS fullness than the control at 15, 30, 45, 60 and 90 min. All subjects ranked inulin control as providing the least VAS fullness for 15, 30, 45 and 60 min.

Table 1
Fullness (iAUC) for VAS in mm and as a rating (1 to 3).

Test food	Area under the curve (iAUC) mean fullness and SD (mm.min)	Area under the curve (iAUC) mean fullness and SD (rating.min)
7.5 g	3942 ^c ± 2250	157.7 ^f ± 90
5 g	2937 ^a ± 1750	117.5 ^d ± 70
2.5 g	3501 ^b ± 2070	140.0 ^e ± 83
0 g	2304 ^a ± 2200*	92.2 ^d ± 88*

Mean values in same column followed by a different letter are significantly different ($P < 0.05$).

* Average of 3 control samples.

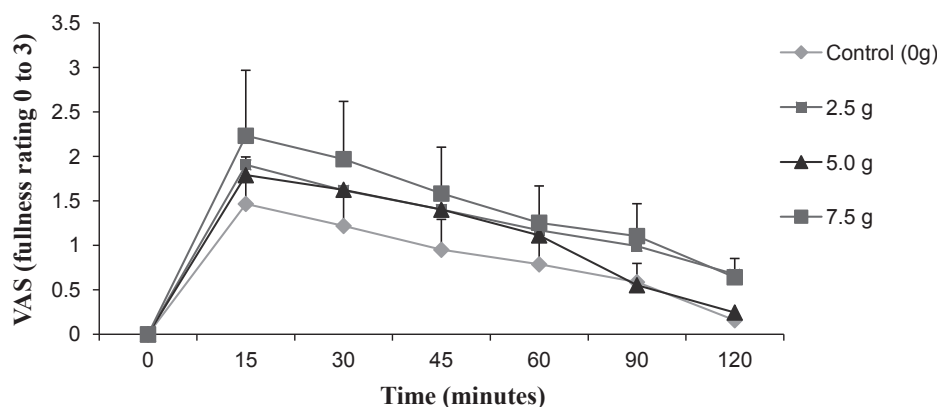


Fig. 2. Visual Analogue Scale – fullness ratings for the question “How hungry do you feel now?” for the control and the 3 doses of PGX[®]. Each symbol is the mean of 10 subjects rating minus the fasting rating.

Relationship with postprandial glycaemia

The same subjects used for the satiety study also had blood samples obtained by finger-prick measured for plasma glucose (mmol/L). Incremental AUC plasma glucose (mmol/L.min) was 151 ± 5 after the consumption of the inulin control, 113 ± 9 after 2.5 g PGX[®], 88 ± 9 after 5 g PGX[®] and 76 ± 9 after 7.5 g PGX[®], showing a negative relationship with fullness iAUC; i.e. as fullness iAUC (0–60 min) increased, plasma glucose iAUC decreased. Both plasma glucose and PGX[®] dose was associated with fullness ($P = 0.01$).

The highest dose of PGX[®] reduced the plasma glucose iAUC by 50% from 151 ± 5 to 76 ± 9 mM/120 min ($P < 0.005$) (previously reported by Brand-Miller et al., 2010). The overall trend for reduction in plasma glucose with increasing dose of PGX[®] was significant, $P < 0.001$. There was no missing data as all subjects completed the study.

Discussion

Significantly greater fullness (VAS) was found from the test meals which included PGX[®], compared with the control meal without PGX[®]. Several factors may have contributed to the higher ratings of fullness, including the viscosity of the PGX[®] fibre, the mixing of the PGX[®] fibre with water prior to consumption, as well as the amount or fibre dose.

Drewnowski (1998) and Ellis, Apling, Leeds, and Bolster (1981) reported the importance of acceptability and palatability in satiety studies. Satiety studies are complex, especially in the study of mixed meals (Hlebowicz, 2009). Mixed meals may be more likeable, but the macronutrients, as well as the physiological properties and the digestibility of the different fibre types and other components of the meal, must be considered. PGX[®], plus white bread was palatable, and enabled the understanding of the role of the PGX[®] in an un-complicated environment.

Our study found the control (5 g inulin) had a much lower effect on satiety compared to PGX[®], but as inulin was part of the control meal with bread, it cannot be concluded that it provides any satiety effect above that of the bread. The inulin dose used as the control in the present study also had no apparent effect on lowering GI in the parallel study (Brand-Miller et al., 2010, 2012). Karalus et al. (2012) also reported that all the fibre in their study (10 g each of oligofructose, inulin, soluble corn fibre or resistant wheat starch), when incorporated into a chocolate crisp product, produced greater gastrointestinal symptoms, but did not alter short-term satiety, hunger or food intake compared with the control.

The negative relationship between fullness and plasma glucose found in this research is supported in research by Keogh, Atkinson, Eisenhauer, Inamdar, and Brand-Miller (2011) who also found a negative relationship between iAUC plasma glucose (mmol/L.min) and feelings of fullness in a study comparing high dietary fibre Burgen bread and lupin bread to white bread.

There appears to be a need for sufficient water for dietary fibre to be effective in providing a satiety effect. Guérin-Deremaux et al. (2011) found fibre in orange juice had an effect on satiety and Calame, Thomassen, Hull, Viebke, and Siemensma (2011) found gum Arabic dissolved in water enhanced satiety. In contrast, products containing fibre, that were consumed dry, even if consumed alongside water, have not supported the case for adding fibre to dry foods. Wanders et al. (2013) found biscuits with added alginate fibre reduced ad libitum intake, but those with guar fibre did not. Neither the biscuits with alginate fibre nor guar fibre affected satiation (Wanders et al., 2013). Mattes (2007) found guar and alginate fibre combinations in a solid food matrix did not affect appetite or acute food intake.

Conclusion

When included as part of a breakfast meal, PGX[®] resulted in increased fullness iAUC and provided an improved satiety effect compared with breakfast without PGX[®]. The findings provide further evidence that satiety and postprandial glycaemia response are connected, and it appears that both may be dictated by viscosity and the effect of blood glucose. Plasma glucose and PGX[®] dose was associated with fullness. A viscous product that forms a gel post consumption to provide a physical feeling of fullness, requires sufficient water to gel, slows gastric emptying, slows the release of glucose into the blood and contributes to the satiety effect would be a powerful satiety agent. PGX[®] forms gel and has a very strong effect on satiety, especially at the 7.5 g dose, and delays the postprandial glycaemia response, but further research is needed to determine if these benefits are to be maintained long term.

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