

## ORIGINAL COMMUNICATION

# A digestive tolerance study of maltitol after occasional and regular consumption in healthy humans

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**Aim:** We aimed to evaluate the gastro-intestinal tolerance to an indigestible bulking sweetener containing sugar alcohol using a double-blind random cross-over study.

**Method:** In order to simulate their usual pattern of consumption, 12 healthy volunteers ingested maltitol or sucrose throughout the day, either occasionally (once a week for each sugar, first period) or regularly (every day for two 9 day periods, second period). In both patterns of consumption, daily sugar doses were increased until diarrhea and/or a grade 3 (ie severe) digestive symptom occurred, at which the dose level was defined as the threshold dose (TD).

**Results:** In the first period (occasional consumption), the mean TD was  $92 \pm 6$  g with maltitol and  $106 \pm 4$  g with sucrose ( $P = 0.059$ ). The mean intensity of digestive symptoms was 1.1 and 1.3, respectively ( $P = \text{NS}$ ). Diarrhea appeared in six and one subjects respectively ( $P = 0.035$ ). In the second period (regular consumption), the mean TD was  $93 \pm 9$  g with maltitol and  $113 \pm 7$  g with sucrose ( $P = 0.008$ ). The mean intensity of digestive symptoms was 1.7 and 1.2, respectively ( $P = \text{NS}$ ). However, diarrhea appeared in eight and three subjects, respectively ( $P = 0.04$ ). Maltitol and sucrose TDs between the two periods were not different.

**Conclusions:** Under our experimental conditions, in comparison to sucrose: (a) occasional or regular consumption of maltitol is not associated with severe digestive symptoms; (b) in both patterns of maltitol consumption, diarrhea frequency is higher, but it appeared only for very high doses of maltitol, much greater than those currently used; (c) maltitol does not lead to intestinal flora adaptation after a 9 day period of consumption.

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### Introduction

Sugar alcohols have been proposed as a replacement for acidogenic sugars in manufactured products because 'high intake of non-milk extrinsic sugars can have undesirable effects on dental health and can predispose obese subjects to undesirable metabolic effects' (COMA, 1994). These polyols are not fermented by oral bacteria and could reduce the incidence of dental caries (Grenby & Philips, 1989). They are considered by some to be neither digested, absorbed nor metabolized to the same extent as sucrose, and thus provide less energy per unit mass to the consumer (Bornet, 1994).

However, this view is currently the subject of controversy (Beaugerie *et al*, 1990).

Because of their physicochemical properties, natural sweetening power and reduced energy value, polyols are used increasingly to replace sucrose in chocolate (Rapaille *et al*, 1994) and other confectionery products (candies, gums) (Rapaille *et al*, 1991). They also find applications in pharmaceutical and cosmetic markets (Rapaille, 1988; Sicart & Le Bot, 1994).

One perceived side-effect to the use of sugar alcohols as alternative bulk sweeteners is an increase in gastro-intestinal symptoms. Maltitol is a sugar alcohol produced by hydrogenation from starch hydrolysates that have a high content of natural disaccharide maltose. After oral ingestion, maltitol is slowly hydrolyzed by the enzymes of the small intestine into its constituent monomers, glucose and sorbitol. The metabolism of maltitol is therefore similar to that of sorbitol. Whereas glucose is easily absorbed and used for energy, the sorbitol moiety is only slowly and incompletely absorbed

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**Table 1** Frequency and mean score of intolerance symptoms intensity<sup>a</sup> after occasional and regular consumption of increasing doses of maltitol in 12 healthy volunteers

Symptoms	Occasional consumption			Regular consumption		
	Maltitol	Sucrose	P	Maltitol	Sucrose	P
Excess flatus	16 (1.1)	7 (1)	NS	20 (1.7)	16 (1.3)	NS
Abdominal pain	11 (1.3)	8 (1)	NS	14 (1.2)	13 (1.4)	NS
Borborygmes	1 (1)	1 (1)	NS	1 (1)	4 (1)	NS
Distending stomach	4 (1)	—	—	7 (1)	3 (2)	NS
Pastille saturation	7 (1.1)	5 (1)	NS	6 (1.5)	5 (2)	NS
Appetite diminution	5 (1.2)	2 (1)	NS	—	1 (1)	—
Sensation of satiety	2 (1)	2 (1)	NS	—	3 (1)	—
Nausea	1 (1)	1 (1)	NS	—	1 (1)	—
Headache	—	—	—	2 (1)	0 (1)	NS
Diarrhea	6	1	0.035	8	3	0.04

<sup>a</sup>Calculated using hedonic scales: 0 = no symptom; 1 = mild, 2 = moderate; 3 = severe.

(Lian-Loh *et al*, 1982; Ziesenitz & Siebert, 1987). It has been recently shown that glycemic and insulinemic indexes of maltitol and maltitol-containing chocolate determined in healthy subjects were low (Pelletier *et al*, 1994). Stool excretion after ingestion of sugar alcohols is negligible, indicating that the sugar alcohols reaching the large intestine are almost completely digested by the colonic flora (Beaugerier *et al*, 1990). However, this malabsorption causes certain side-effects, as fermentation of unabsorbed sugar leads to flatulence. In addition, as polyol molecules are osmotically active, diarrhea may occur when the capacity of the colonic flora to ferment these low-molecular-weight carbohydrates is exceeded and osmotic stress rises in the intestinal lumen (Hammer *et al*, 1989; Saunders & Wiggins, 1981).

The capacity to ferment unabsorbable sugars, such as lactose and lactulose, and to reduce their laxative effects can, however, be increased by regular ingestion of these sugars, which results in changes in the metabolic activity of the colonic flora, especially a reduced excretion of hydrogen in the breath (H<sub>2</sub>) (Florent *et al*, 1985; Flourié *et al*, 1993; Launiala, 1968; Perman *et al*, 1981).

The present work investigates the occurrence of severe digestive symptoms and diarrhea, and compares their severity when maltitol is consumed regularly or occasionally.

## Subjects and methods

The digestive tolerance to maltitol (Cerestar Cereal, Brussels, Belgium) and sucrose was determined in healthy volunteers in a double-blind, randomized cross-over study. Test products were then identical except for their added carbohydrate ingredient and were supplied by Cerestar, Vilvoorde R&D Centre, Belgium. Maltitol and sucrose were each used as sole sweeteners in milk chocolate bars identical in appearance, color and taste. The 100 g bar contained 42 g bulk sweetener as either sucrose (S) or maltitol (M) (4-O-D-glucopyranosyl-D-sorbitol). Both 100 g milk chocolate bars contained 35 g fat, 21 g protein and 2 g lactose. Sweetness levels were not adjusted by addition of intense sweetener. Bars had identical wrappers, which were distinguished by codes that

were not revealed to the investigators until after the completion of the study. The chocolate bars were consumed occasionally and regularly.

## Subjects

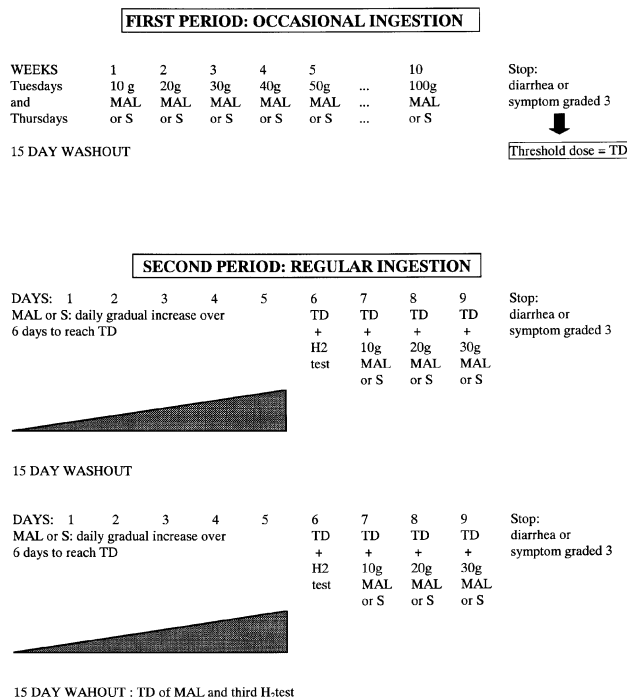
Twelve volunteers (all males, aged between 18 and 45 y), with mean body-weight  $\pm$  10% of their ideal weight (71  $\pm$  2 kg, mean  $\pm$  s.d.), were included in this study. None had a history of gastro-intestinal disease, or antibiotic or laxative use for the previous 3 months. All of them were lactose absorbers as tested by a H<sub>2</sub> breath test after ingestion of 50 g of lactose in water. They gave informed consent to the protocol which was approved by the Consultative Committee for the People involved in Biochemical Research (CCPPRB) of Saint-Germain-en-Laye (78104, France).

## Experimental design

Tolerance to maltitol was assessed over two test periods, separated by at least 15 days, each corresponding to different maltitol consumption patterns (Figure 1).

In the first period, maltitol consumption was occasional, ie one dose of maltitol and sucrose was tested at random on Tuesdays and Thursdays of each week for 10 weeks. Thus, to avoid any adaptation, subsequent ingestions of maltitol were separated by at least 5 days, with the number of intakes per day between 3 and 6. The starting dose was 10 g per day (ie two chocolate bars). Each consecutive week, the daily sugar dose was increased by 10 g until bad digestive tolerance occurred, defined as diarrhea and/or a symptom of grade 3 (ie severe) indigestion. This dose was defined as the threshold dose (TD).

In the second period, subjects were asked to consume the same sugar (either maltitol or sucrose) every day according to an increasingly intensive schedule lasting at most 9 days; in the same manner, they consumed the other sugar after a wash-out period of 2 weeks. In this way, consumption of maltitol was initiated cautiously with a gradual increase over subsequent days. The first dose was 25% of the TD as defined



**Figure 1** Experimental design showing the occasional and regular consumption of maltitol (MAL) and sucrose (S). In the two patterns of consumption, daily sugar doses were increased until diarrhea and/or a grade 3 symptom occurred.

in the first period, increasing to 33, 50, 66 and 75% of this dose. According to the schedule, subjects reached the TD found in the first period on the 6th day of each 9 day part of the second period. Afterwards, this dose plus 10, 20 and 30 g extra was consumed by each subject on days 7, 8 and 9, respectively. As in the first period, subjects were told to stop sugar ingestion if diarrhea and/or a grade 3 symptom occurred.

On day 6 of each 9 day period of maltitol and sucrose consumption, an H<sub>2</sub> breath test was performed which was repeated 2 weeks after the end of the second administration period. Basely and at 60 min intervals until either 10 h or a return to basal value after awakening, end alveolar samples were collected and analyzed for H<sub>2</sub> using an electrochemical cell (GMI, Renfrew, UK). Fifteen days after the conclusion of the study, breath H<sub>2</sub> excretion was again assessed before and after maltitol ingestion in the same way as for the previous H<sub>2</sub> breath tests. This last breath test was expected to show a higher excretion of H<sub>2</sub> than that measured for the same daily load during chronic consumption of maltitol. On the three days during which breath tests were performed, meals were standardized, and special care was taken in order that the timing of meal and chocolate bar ingestion was identical. The hydrogen and methane concentrations in breath samples were determined simultaneously with Microlyser gas chromatography (Quintron Instrument Company, Milwaukee, WI, USA) using a molecular sieve column (12' Hysep Q, 60/80 mesh; Quintron Instrument Co.).

On the days of sugar administration in both periods: (a) subjects were instructed not to consume sugar at the beginning or end of the day, ie as a substitute breakfast or as a late night snack. Ideally, we wanted subjects to incorporate consumption into their normal dietary habits. Subjects were also asked to spread their consumption of chocolate bars during the day in three to six intakes. (b) Subjects were asked to avoid high consumption of certain foods known to promote abdominal symptoms or containing sugar alcohol: white beans, onions, cabbage, Brussels sprouts, sauerkraut, raisins, bananas, apricots, apples, plum juice, apple, grape, wholemeal bread, bran bread, bran, breakfast cereals, milk and dairy products (cream cheese, yogurts, any kind of cheese, cream, dairy cream, cream pastries, non-home-made ready-cooked dishes, milk chocolate, caramels, non-home-made cookies) and 'light' products. (c) Subjects were asked to fill a diary card containing the following: timing of daily meals, timing and number of chocolate bars ingested, occurrence of the following symptoms: borborygmi, excess flatus, abdominal pain, distended stomach, nausea, vomiting, fever, sensation of satiety, appetite diminution, headache, insomnia, thirst and pastille saturation. Each symptom was graded as 0 (none), 1 (mild), 2 (moderate) and 3 (severe); a gradation of 3 indicating avoidance of the product in the future. Diarrhea was defined as three or more stools per day. This card was checked by the investigator in the presence of the volunteer in the unit at 07.00 am on each administration day.

### Calculations and statistics

In both periods, we defined the occurrence dose for each symptom as the first dose from which a symptom was graded by a subject. For each subject, a total score was calculated as being equal to the sum of scores for each symptom on the auto-evaluation card. Thus, a cumulative score was calculated over weeks and over days for both occasional and regular consumption periods. Regarding the cumulative total score, maltitol and sucrose were compared using a Wilcoxon signed-rank test. Regarding the diarrhea symptom, the incidence was evaluated to compare maltitol and sucrose using a chi-square test.

Bad digestive tolerance doses defined as TD were tabulated for the first period and for each 9 day part of the second period. Those reported for maltitol were compared between the two periods using a Wilcoxon signed-rank test. If a subject reached the TD as defined above without experiencing some of the symptoms, it was assumed that these symptoms would have occurred at the next step dose. The mean occurrence dose for all symptoms was thus calculated from the 12 subjects.

Hydrogen excretion was quantified by using a trapezoidal method for computing the area under the discontinuous curve of breath H<sub>2</sub> concentration. Tidal volumes were determined from the Radford nomogram (Radford *et al*, 1954) and data were expressed in milliliters per 10 h (Solomons *et al*, 1977). The three measurements of the H<sub>2</sub> breath test were

compared using a Wilcoxon signed-rank test. A *P*-value of less than 0.05 was considered to be statistically significant. Results were expressed as mean  $\pm$  s.d.

## Results

### First period: occasional consumption

While consuming sucrose, one subject reached the TD (diarrhea with 60 g). While consuming maltitol, the TD was reached in six subjects who experienced diarrhea with a mean dose of  $63 \pm 9$  g. The mean TD was  $92 \pm 6$  g with maltitol and  $106 \pm 4$  g with sucrose ( $P=0.059$ ). Frequency and mean scores of digestive symptoms are reported in Table 1. The most common symptoms noted with maltitol were excess flatus and abdominal pain; the mean intensity of these symptoms was mild, 1.1 and 1.3 respectively (NS). Diarrhea appeared in six and one subjects during maltitol and sucrose consumption, respectively; this difference was significant ( $P=0.035$ ).

### Second period: regular consumption

While consuming sucrose, the TD was reached in five subjects: two experienced diarrhea with a mean dose of  $90 \pm 0$  g, two recorded severe abdominal pain with a mean dose of  $57 \pm 12$  g; one subject experienced two severe effects of diarrhea and pastille saturation. While consuming maltitol, the TD was reached in 10/12 subjects. Among them, eight subjects experienced diarrhea with a mean dose of  $69 \pm 10$  g, one recorded pastille saturation with a mean dose of 100 g and one recorded excess flatus with a mean dose of 120 g. The mean global TD was  $93 \pm 9$  g for maltitol and  $113 \pm 7$  g for sucrose consumption ( $P=0.008$ ). Frequency and mean scores of digestive symptoms are reported in Table 1. The most common symptoms noted with maltitol were excess flatus and abdominal pain, with a mean intensity of 1.7 and 1.2, respectively (NS). Diarrhea appeared in eight subjects with maltitol and in three subjects with sucrose; this difference was significant ( $P=0.04$ ). Hydrogen excreted in breath was higher with maltitol than with sucrose on a regular consumption basis ( $121 \pm 68$  vs  $16 \pm 21$ ;  $P=0.003$ ) but was not different during occasional or regular consumption ( $121 \pm 68$  vs  $131 \pm 51$  ml/10 h,  $P=0.83$ ) of maltitol.

The maltitol and sucrose TD between the two periods, ie occasional consumption, were not different ( $P=0.615$  and 0.19, respectively).

## Discussion

The present study demonstrates that, compared to reactions which occur after the consumption of standard sucrose-containing chocolate, occasional or regular consumption of increasing doses of maltitol is not associated with significant digestive symptoms, but results in an increase in diarrhea. Diarrhea was the commonest reason for withdrawing from

the study. Tolerance to slowly absorbed bulking sweeteners such as sugar alcohols is commonly evaluated by fasting healthy volunteers eating large or increasing amounts of the test substance on its own, diluted in water. However, in real life, individuals do not usually ingest a large load of such sugar-free products at one time in a fasted state, but rather eat smaller amounts throughout the day during or after meals as confectionery or pastry. In addition, individuals may consume slowly absorbed bulk sweeteners occasionally or regularly. It was the aim of our study to compare digestive tolerance when maltitol was ingested throughout the day in sugar-free chocolate bars with these two patterns of consumption.

When a slowly absorbed carbohydrate is occasionally ingested, the colonic flora is not adapted to this substance. This could explain why different symptoms are closely correlated with the dose of unabsorbable sugar that reaches the colon (Briet *et al*, 1995a,b). The tolerance of sugar alcohols varies considerably between subjects and it has been reported to be dose-dependent (Dharmaraj *et al*, 1987; Krüger *et al*, 1991; Livesey, 1990). However, we could not find such dose-dependency from a review of the literature. In a recent study performed on ileostomy subjects who consumed maltitol over a 3 day period, absorption accounted for 91% of ingested maltitol hydrolyzed in the ileostomy effluent (Langkilde *et al*, 1994), which was in close agreement with the 89% found by the ileal aspiration technique (Beaugerie *et al*, 1990). This study also showed that the levels of digestion and absorption of two sugar alcohols (sorbitol and isomalt) were dose-dependent, which can influence digestive tolerance. A double-blind cross-over study performed on 59 healthy volunteers has shown that an acute oral intake of 30 g of maltitol in milk chocolate resulted in no significant increase in reported digestive symptoms, except mild flatulence (Koutsou *et al*, 1996). Although 40 g of maltitol resulted in an increase in borborygms, abdominal pain and flatus ( $P < 0.01$ ), all three symptoms were ranked only as mild. In our study we found such symptoms, but at higher doses of maltitol, probably because it was mainly taken during or after meals. In the study of Koutsou *et al* (1996), the incidence of diarrhea was not significantly higher than after consumption of chocolate containing only sucrose, which suggests that the colonic fermentative capacity had not been exceeded. These results had been confirmed in another double-blind cross-over study performed on 20 healthy volunteers who ingested 30 g of maltitol in chocolate without significant symptomatology; however, 40 g caused mild borborygmi and flatus but no diarrhea (Storey *et al*, 1998). In our study, diarrhea was not more common with maltitol than with sucrose when consumption was occasional, probably because the sugar ingestion throughout the day decreases the osmotic load. However, this apparent good intestinal tolerance must be balanced by individual susceptibility to indigestible carbohydrates, as certain subjects can experience digestive intolerant symptoms at relatively low doses.

Prolonged ingestion of slowly absorbed sugars, such as lactose and lactulose, results in changes in the metabolic activity of the colonic flora, especially a fall in breath excretion of H<sub>2</sub>, which increases its ability to ferment the sugar (Florent *et al*, 1985; Flourié *et al*, 1993; Launiala, 1968; Perman *et al*, 1981). As a result, there is efficient fermentation of the chronically ingested unabsorbed sugar, and thus a reduction in its diarrhoeogenic effect (Rambaud & Flourié, 1994). On the other hand, this more efficient fermentation might increase the total intra-colonic production of bacterial gases other than H<sub>2</sub>, and might affect flatulence. Thus, the results of our study were unexpected. Regular consumption of maltitol did not lead to an increase in rectal gases and we did not observe a decrease in breath H<sub>2</sub> production when compared with occasional consumption. Therefore, regular consumption of maltitol did not lead to an adaptation of colonic flora, which seems variable with different unabsorbable sugars (Stone-Dorchow & Levitt, 1987; Briet *et al*, 1995a,b). However, these conclusions need to be treated with caution, as the duration of maltitol consumption was relatively short, and we cannot exclude the possibility of colonic flora adaptation for a longer duration of intake (Olesen *et al*, 1994).

Under our experimental conditions, in comparison to sucrose, occasional or regular consumption of maltitol is not associated with severe digestive symptoms. Diarrhea frequency is higher in both patterns of maltitol consumption, but it appeared only for very high doses of maltitol, much greater than those currently used. Conversely, using doses of less than 50 g of maltitol per day, almost no symptoms occurred.

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