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The comparative gastrointestinal response of young children to the ingestion of 25 g sweets containing sucrose or isomalt

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Sugar-free confectionery products containing the low-energy, non-cariogenic sweetener isomalt are widely available in the market place and increasingly aimed at children. However, over-consumption of such products may lead to gastrointestinal symptoms and/or osmotic diarrhoea. Little is known about the gastrointestinal tolerance of children following consumption of isomalt. The aim of the present study was to assess gastrointestinal symptoms in children following consumption of sugar-free confectionery containing isomalt compared with sweets containing sucrose. In a double-blind, randomised, controlled, crossover study, sixty-seven children aged 6–9 years ingested 25 g hard-boiled sweets containing either sucrose or isomalt on two consecutive test days. Isomalt sweets were received as enthusiastically as sucrose sweets and, when given the choice, 97 % of children asked to be given the isomalt or the sucrose sweets on the second test day. Most children did not report multiple symptoms and few experienced symptoms on both days of isomalt consumption. However, significantly more children reported stomach-ache ($P<0{\cdot}01$), abdominal rumbling ($P<0{\cdot}025$) and passing watery faeces ($P<0{\cdot}001$) following consumption of isomalt sweets compared with sucrose sweets. Consumption of 25 g isomalt-containing sweets by children is not associated with significant gastrointestinal effects graded as 'considerably more than usual' or multiple symptoms, but is associated with a laxative effect and increase in symptoms graded as 'slightly more than usual'. For the majority of children in the present study, 25 g isomalt-containing sweets represents an acceptable level of consumption, although some children are sensitive to the effects of isomalt ingestion.

Gastrointestinal response: Isomalt: Sucrose: Sweets: Children

Sucrose derived from confectionery products makes a significant contribution to total non-milk extrinsic sugar and total energy intake in the diets of children and is a risk factor in the development of dental caries (Department of Health, 1989; Rugg-Gunn *et al.* 1993; Adamson, 1994). In these respects, the polyol sugar isomalt (an approximate equimolar mixture of the stereoisomers α-D-glucopyranosyl-1,6-D-sorbitol and α-D-glucopyranosyl-1, 1-D-mannitol) is an excellent alternative to sucrose because it is minimally caries-promoting (Imfeld, 1983, 1993; Featherstone, 1994). It is ideal for formulation into confectionery foods because of its reduced energy value and similar physico-chemical properties to sucrose. A wide variety of isomalt-based, tooth-friendly, low-energy confectionery products is now available to the consumer. Many of these are aimed at children because of their reduced cariogenicity compared with classical confectionery products containing sucrose as the bulk sweetener (Zumbé *et al.* 1994, 2001).

Isomalt is incompletely hydrolysed and/or absorbed in the small intestine resulting in delivery of intact isomalt and its hydrolysis products, sorbitol and mannitol to the large intestine (Grupp & Siebert, 1978; Nilsson & Jagerstad, 1987; Langkilde *et al.* 1994). These components are osmotically active which may lead to intestinal hurry, and if the water reabsorption capacity of the colon is exceeded, osmotic diarrhoea (Saunders & Wiggins, 1981; Hammer *et al.* 1989; Rambaud & Flourié, 1994). Thus, ingestion of isomalt (in common with other polyols) may provoke intolerance symptoms due to osmotically-induced fluid entry into the gut and formation of intestinal gas following fermentation of hydrolysed and/or intact polyol entering the colon (Menzies, 1983; Billaux *et al.* 1991; Livesey, 2001).

Abbreviation: GI, gastrointestinal.

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Ingestion of isomalt is associated with increased colonic fermentation confirming its potential to cause excess flatulence, stomach-ache, abdominal bloating and rumbling noises (Fritz & Siebert, 1985; Lee *et al.* 1994). Daily doses of up to 50 g are generally tolerated well by healthy adult volunteers but with increased, though not always significant, intolerance symptoms (Bachmann *et al.* 1984; Spengler *et al.* 1987; Zumbé & Brinkworth, 1992; Koutsou *et al.* 1996). Ingestion of up to 35 g isomalt in chocolates by children aged 8–18 years reportedly causes no significant increases in intolerance symptoms including osmotic diarrhoea (Paige *et al.* 1992). However, very little is known about the gastrointestinal responses of young children following consumption of isomalt (or other polyols) and it's potential to provoke painful intolerance symptoms or a laxative effect. Because sugar-free products containing isomalt are widely available to children and the occurrence of gastrointestinal (GI) symptoms following polyol ingestion in this age group give cause for concern, the aim of the present study was to compare the GI response of young children aged 6–9 years following ingestion of two doses of 25 g hard-boiled sweets containing either sucrose or isomalt as the bulk sweetening agent.

Subjects and methods

Subjects were 6–9-year-old school children recruited from three primary schools in the Salford area of Greater Manchester, UK, following information about, and an invitation to, the study by letter. The childrens' parents gave written consent for them to participate in the study and ethical approval was given by the Salford Health Authority Regional Ethics Committee. Approval was also given by the Salford Local Education Authority and by headteachers of the schools involved. The children gave verbal consent and were free to leave the study at any time and for any reason. Upon completion of the study each child was given a free 'Sympadent' T-shirt bearing the international tooth-friendly logo, and each participating school was provided with some financial help to purchase teaching aids for the children of their school.

Pre-screening of children ensured that they did not have a history of either GI or metabolic disease, were not subject to any dietary restrictions, prescribed diets or supplementary fibre intake, did not suffer from food allergies and did not regularly consume polyol-containing confectionery products. It also ensured that children had not received antibiotics, steroids, laxatives or any other drugs for 1 month before the study. These exclusions were applied for the 2-week study period and any medication had to be reported, enabling the child's suitability for continued participation to be reassessed. No child was excluded during the course of the study on these grounds. Sixty-seven children were initially recruited and fifty-eight children successfully completed the study; thirty were boys and twenty-eight were girls with mean ages of 8·4 (SD 0·7) and 8·2 (SD 0·8) years respectively. There were no significant differences in age between either boys or girls or children from different schools.

Test materials

Test products were identical except for their added carbohydrate content and were supplied as packets of hard-boiled sweets containing ten pieces with an assortment of flavours. An independent analysis carried out by the Research and Development Department of Südzucker, Mannheim, Germany, confirmed that the sucrose-containing sweets contained (g/kg): sucrose 689, glucose 137, residual saccharides 134, water 4, the isomalt-containing sweets contained (g/kg): isomalt 853, maltitol 49, residual saccharides 69, water 29. Sweetness levels were adapted by the addition of 1000 mg acesulfame K/kg. Sweets were packaged in a silver-foil wrapper bearing one of six code numbers and a 'Mario'® cartoon character to make the product more attractive to children. Product identity was not revealed to the study investigators until after completion of the study.

Study design

Children were given each product in a double-blind, controlled crossover study with each coded product being allocated in random order determined by a Latin square design applied to each leg of the study. Twenty-nine children received sucrose sweets (25 g) on test days 1 and 2 of the study and isomalt sweets (25 g) on test days 10 and 11. The other group of twenty-nine children first consumed isomalt sweets on test days 1 and 2 of the study before crossing over to consume sucrose sweets on test days 10 and 11 of the study. A washout period of 7 d was incorporated into the study between consumption of alternative products. Test products were distributed each day to avoid over-consumption and confusion over which product to consume. Children were invited, but not forced, to consume all the sweets in each packet given to them and they were allowed to consume them over any period of time that they chose. Most children ate their sweets in class, being supervised by the study investigators or class teachers, but a few ate them during break time. Following consumption of product on test day 1, children were asked if they would like to eat another packet of the same type of sweet on a second day or whether they would like to move straight on to the next product in a week's time and so complete the study. Only three children out of the sixty-seven recruited initially wished to consume a product once only.

Study restrictions

The consumption of milk and fresh fruit juice was restricted to no more than one glass, (approximately 200 ml) of each for 12 h before test days, the 24 h of test days and 12 h thereafter. On the day following consumption of each test product, children were individually interviewed (not in the immediate presence of a parent or schoolteacher), according to a set protocol to determine if they had adhered to study restrictions and consumption regimen or if they had experienced any GI responses. No child, class teacher or parent reported over-consumption of milk or fruit juice during periods of restriction. Questions

relating to taste and the occurrence of thirst, loss of appetite and nausea were included to minimise focusing on GI functions and as a means of gaining children's confidence.

Gastrointestinal responses

Children were asked if they had 'experienced any unusual feelings' during the 24 h period following consumption of test products. Then children were asked how many bowel movements they had made, the consistency of faeces passed and if they had experienced a feeling of fullness, wind, stomach-ache or abdominal rumbling noises. During interviews various terms and descriptions of symptoms were used which were familiar to children, e.g. watery faeces as a 'runny bottom', etc. Children sometimes volunteered information regarding GI responses without being prompted by the study investigators. However, they were specifically asked if they had experienced any response not already mentioned. Children were then asked to describe 'how much' response they had felt, where: normal (0), nothing more than usual. A scale was then erected to include three increasing levels of response. These were: 1, 'a little more than usual'; 2, 'noticeably more than usual'; 3, 'considerably more than usual'. Bowel movements to pass normal, watery or hard faeces were counted as none (0) or as the actual number of events per d. Because children were not monitored during toilet visits, information about faecal volume was not collected.

Table 1. Total occurrence of gastrointestinal responses after consumption of 25 g sweets containing either sucrose or isomalt by children (*n* 67) on two test days*†

	Sucrose		Isomalt	
Gastrointestinal responses	*n*	%	*n*	%
Fullness (grade)‡				
0	117	87·31	117	87·31
1	11	8·21	12	8·96
2	6	4·48	2	1·49
3	0	0·00	3	2·24
Total	17	12·69	17	12·69
Wind (grade)‡				
0	109	81·34	94	70·15
1	19	14·18	20	14·93
2	2	1·49	10	7·46
3	4	2·99	10	7·46
Total	25	18·66	40	29·85
Stomach-ache (grade)‡				
0	116	86·57	90	67·16
1	11	8·21	20	14·93
2	2	1·49	12	8·96
3	5	3·73	12	8·96
Total	18	13·43	44	32·84
Abdominal-rumbling noises (grade)‡				
0	120	89·55	101	75·37
1	13	9·70	15	11·19
2	1	0·75	11	8·21
3	0	0·00	7	5·22
Total	14	10·45	33	24·63
Watery faeces (*n*)				
0	129	96·27	107	79·85
1	5	3·73	18	13·43
2	0	0·00	3	2·24
3+	0	0·00	6	4·48
Total	5	3·73	27	20·15

* For details of subjects and procedures, see p. 292.
† *n* 134.
‡ Grade: 0, normal; 1, a little more gastrointestinal response than usual; 2, noticeably more gastrointestinal response than usual; 3, considerably more gastrointestinal response than usual.

Statistics

Childrens' responses were categorical (yes/no) and thus data were treated as non-parametric. The numbers of children experiencing responses were analysed for product effect taking account of order and for order effect alone, by 2×2 contingency tables using an exact test attributable to Gart (1969). The occurrence of multiple responses was analysed by χ^2 test.

Results

Of the sixty-seven children recruited initially, fifty-eight completed the study and consumed sucrose and isomalt sweets on two days. Of those who did not complete the study, two children had mild stomach-ache and were withdrawn by their parents even though both children wished to continue with the study; two children were absent from school and could not complete the study; three children wished to consume sucrose or isomalt sweets on only one day and two children forgot to consume their sweets on appropriate study days. Analysis of results has been performed on 'an intend to treat' (*n* 67) and not 'per protocol' (*n* 58) basis and thus includes any GI responses of these children.

Most children were eager to participate in the study and consumed all ten sweets in each packet provided for them. Only six packets of sucrose sweets and eight packets of isomalt sweets out of 116 packets of each product provided were left unfinished. However, even in these cases, each child consumed at least seven sweets out of the ten provided.

Although no set consumption pattern was enforced, the time taken for children to consume their sweets was recorded. The children consumed the sweets with enthusiasm and seventy-two packets of sucrose sweets and sixty-nine packets of isomalt sweets out of 116 of each provided were consumed by children in less then 30 min.

Most children felt happy with the sweets and the occurrence of GI responses did not prevent the children from asking for more. Even the few children who reported a high frequency of responses did not regard them as negative, painful or harmful. Indeed the children were very keen to report whenever they had a response.

Table 1 shows the total incidence of GI responses in the 24 h post-consumption period following ingestion of sucrose or isomalt products over 2 d for sixty-seven children. There was no increase in the reporting of fullness after eating isomalt sweets compared with sucrose sweets, but stomach-ache, wind, abdominal rumbling noises and bowel movements to pass watery faeces were all increased following consumption of isomalt sweets compared with sucrose sweets. Many of the reported responses were rated as 'a little more than usual' but stomach-ache, wind and

abdominal-rumbling noises were more often rated as grade 2 or 3 responses following consumption of isomalt sweets compared with sucrose sweets.

The sixty-seven children reported a total of eighty-four bowel movements to pass faeces of any consistency following consumption of sucrose sweets over 2 d compared with 114 bowel movements for isomalt sweets. There were forty-four bowel movements consisting of watery faeces following consumption of isomalt sweets compared with five following consumption of sucrose sweets ($P<0{\cdot}001$).

Because each child consumed the sucrose and isomalt sweets on two occasions, the numbers experiencing symptoms may be partitioned into those experiencing symptoms on only one test day or on both test days following consumption. These data are shown in Table 2 together with the total number of children reporting responses on only one test day and on both test days. Significantly more children reported stomach-ache and abdominal-rumbling noises of any grade ($P<0{\cdot}01$ and $P<0{\cdot}025$ respectively), and grades 2 and 3 ($P<0{\cdot}025$ and $P<0{\cdot}005$ respectively), after consuming isomalt sweets compared with sucrose sweets. There were no significant differences in the number of children reporting the sensations of wind or fullness after consumption of either product on 2 d.

There was no significant difference in the numbers of children making one or more bowel movements to pass faeces of any consistency following consumption of sucrose or isomalt sweets on 2 d. Significantly more children made one or more, and two or more bowel movements to pass watery faeces following consumption of isomalt sweets compared with sucrose sweets ($P<0{\cdot}001$ and $P<0{\cdot}0025$ respectively). Only one child made more than three bowel movements (actually four) to pass watery faeces on both days of isomalt consumption. The same child made two bowel movements to pass normal faeces on both days of sucrose consumption. The order of product consumption had no significant effect on the numbers of children experiencing GI responses ($P>0{\cdot}05$).

Table 3 shows the occurrence of multiple responses following consumption of sucrose and isomalt sweets over two test days. In total, more children experienced two, three, four or five responses following consumption of isomalt sweets compared with sucrose sweets. No child experienced more than three symptoms following consumption of sucrose sweets but a few children experienced

Table 2. The number of children reporting gastrointestinal responses on only one test day or both test days after consumption of 25 g sweets containing either sucrose or isomalt*‡

	Sucrose			Isomalt		
Gastrointestinal responses	One test day only	Both test days	Total	One test day only	Both test days	Total
Fullness (grade)§						
0	55	65	53	56	64	53
1+2+3	12	2	14	11	3	14
2+3	6	0	6	3	1	4
3	0	0	0	1	1	2
Wind (grade)§						
0	56	60	49	45	59	37
1+2+3	11	7	18	22	8	30
2+3	5	0	5	11	2	13
3	4	0	4	8	1	9
Stomach-ache (grade)§						
0	55	64	52	43	57	33
1+2+3	12	3	15	24	10	34**
2+3	7	0	7	16	4	20††
3	4	0	4	6	3	9
Abdominal-rumbling noises (grade)§						
0	59	64	56	48	60	41
1+2+3	8	3	11	19	7	26††
2+3	1	0	1	9	4	13†††
3	0	0	0	6	1	7††
Bowel movements*						
0	44	48	25	40	45	18
1+	23	19	42	27	22	49
2+	10	4	14	12	7	19
3+	3	0	3	8	2	10
Watery faeces*						
0	62	67	62	48	63	44
1+	5	0	5	19	4	23***
2+	0	0	0	7	1	8††
3+	0	0	0	4	1	5

* Total *n* 67.
‡ For details of subjects and procedures, see p. 292.
§ Grade: 0, normal; 1, a little more gastrointestinal response than usual; 2, noticeably more gastrointestinal response than usual; 3, considerably more gastrointestinal response than usual.
Values were significantly different from those for the sucrose product: ††$P<0{\cdot}025$, **$P<0{\cdot}01$, †††$P<0{\cdot}005$, ***$P<0{\cdot}001$.

Table 3. Gastrointestinal responses reported by children (*n* 67) after consumption of 25 g sweets containing either sucrose or isomalt on one or two occasions*

	1st consumption occasion				2nd consumption occasion			
	Sucrose		Isomalt		Sucrose		Isomalt	
Gastrointestinal responses (*n*)†	*n*	%	*n*	%	*n*	%	*n*	%
No response	39	58·21	30	44·78	46	68·66	29	43·28
One GI response	15	22·39	15	22·39	10	14·93	10	14·93
Two GI responses	10	14·93	15	22·39	7	10·45	14	20·90
Three GI responses	3	4·48	3	4·48	4	5·97	11	16·42
Four GI responses	0	0·00	3	4·48	0	0·00	3	4·48
Five GI responses	0	0·00	1	1·49	0	0·00	0	0·00

GI, gastrointestinal.
* For details of subjects and procedures, see p. 292.
† GI responses were: fullness; wind; stomach-ache; abdominal-rumbling noises; watery faeces.

four or five symptoms following consumption of isomalt sweets. These differences were not significant.

Discussion

The GI response of adults following consumption of isomalt or isomalt-containing foods is well documented (Fritz & Siebert, 1985; Zumbé & Brinkworth, 1992; Lee *et al.* 1994; Koutsou *et al.* 1996). However, very little information is available regarding GI function in children after consumption of isomalt or other polyols. This is surprising, considering that the occurrence of watery faeces or painful abdominal responses following polyol consumption by children might be considered a sensitive issue (Stewart, 2001). Paige *et al.* (1992) reported that in both children and teenagers there was no significant or dose-dependent increase in symptoms following consumption of 15, 25 and 35 g isomalt given in chocolate compared with sucrose controls. These findings are at variance with the results of the present study and those of Koutsou *et al.* (1996), who demonstrated significant and dose-dependent increases in GI responses following consumption of 30 and 40 g isomalt, lactitol and maltitol given in milk chocolate to young adults. However, it is possible that the high percentage of fat in chocolate may delay gastric emptying and partition the dose of polyol entering the small intestine and subsequently the large intestine thereby mediating any intolerance effect. For this and other reasons, it may be difficult to compare GI responses following consumption of chocolate containing polyols with those following consumption of sweets composed almost entirely of polyols.

Children in the present study generally opened their bowels relatively infrequently, which may indicate a diet low in dietary fibre. Vitolo *et al.* (1998) reports that constipated children have lower estimated dietary fibre intakes compared with children with normal bowel movements and Osatakul *et al.* (1995) reports that Thai children with large dietary fibre intakes pass softer, larger and more frequent stools compared with western children. Relatively little data concerning the bowel habits of healthy children exists, but Bloom *et al.* (1993) report a mean figure of 6·8 (SD 2·5) bowel movements/week for children aged 3–12 years. This value, when translated into a mean of 0·971 bowel movements/d is similar to the value of 0·851 bowel movements/d following consumption of isomalt sweets by children in the present study. However, bowel-movement frequency in children (as with adults) ranges considerably from 1 to 21/week (Bloom *et al.* 1993).

Diarrhoea may be defined as the passage of one or more watery faeces per d or more than three stools per d (Marteau & Flourié, 2001). Using this definition, a significant laxative effect was associated with consumption of isomalt sweets. However, this effect was confined to a significant increase in the number of children making one or two bowel movements to pass watery faeces but not one or more bowel movements to pass faeces of any consistency. Thus, isomalt promoted more of a change in faecal consistency rather than bowel-movement frequency, i.e. watery faeces were passed at the expense of faeces of normal consistency. In comparison, the consumption of 30 and 40 g isomalt in milk chocolate has been shown to increase significantly the number of adults making bowel movements to pass one or more watery faeces but not three or more bowel movements to pass watery faeces (Koutsou *et al.* 1996).

Table 2 shows that most children experienced GI responses on one test day only. Taken over 2 d, there was no significant difference in the number of children reporting a feeling of fullness or wind following consumption of isomalt sweets compared with sucrose sweets. However, significantly more children reported stomach-ache and rumbling noises of any grade ($P<0·05$ in both cases), and grades 2 and 3 ($P<0·005$ in both cases), after consuming isomalt sweets compared with sucrose sweets. Only three children reported their stomach-ache to be considerably more than normal on both days of isomalt consumption compared with none following consumption of sucrose. Perhaps such children might be regarded as sensitive to the effects of ingestion of isomalt sweets and deterred from eating them. Nevertheless, some children still reported grade 3 symptoms (stomach-ache and wind) following consumption of sucrose sweets. Such inter-subject variability in the tolerance of poorly digested carbohydrates is probably due to differences in absorption capacities, motility patterns, colonic responses and intestinal sensitivity as described by Marteau & Flourié

(2001) as well as other factors such as dietary factors and composition of the colonic flora (Cummings *et al.* 2001).

Table 3 shows that following consumption of isomalt sweets by children more than one GI response may be experienced. In total seven children reported three or more different responses on the first day of consumption of isomalt sweets compared with three following consumption of sucrose sweets. On the second day, fourteen children reported three or more symptoms following consumption of isomalt sweets compared with four following consumption of sucrose sweets. It may be considered that multiple responses, even of a mild nature (grade 1), could cause a degree of discomfort equivalent to a single response experienced at a more noticeable level (e.g. grade 3). However, only one child reported all five symptoms following consumption of the isomalt sweets on one day, and even then wanted to continue with the study.

Very few children reported either grade 3 responses, had three or more bowel movements when watery faeces were passed, or experienced more than three different responses following consumption of isomalt sweets. These findings correspond to results from adult studies with similar patterns of tolerance following ingestion of poorly digested sugar-substitutes (Fritz & Seibert, 1985; Zumbé & Brinkworth, 1992; Lee *et al.* 1994; Storey & Zumbé, 1995; Koutsou *et al.* 1996; Lee & Storey, 1999). Furthermore, it is notable that children expressed equal preference for sucrose and isomalt sweets. Both were received and consumed equally enthusiastically by children and no child expressed a desire to leave the study because of GI responses. In conclusion, consumption of 25 g isomalt-containing sweets by children is not associated with significant GI effects graded as 'considerably more than usual' or multiple symptoms, but is associated with a laxative effect and increase in symptoms graded as 'slightly more than usual'. For the majority of children in the present study, 25 g isomalt-containing sweets represents an acceptable level of consumption although some children are sensitive to the effects of isomalt ingestion. However, these effects are transient and stopping consumption of polyols such as isomalt mitigates symptoms (Storey & Lee, 2001). In order to limit potential GI symptoms following isomalt ingestion it is recommended that children consume no more than 25 g isomalt-containing sweets/d in addition to their normal unrestricted diet that may contain other low-digestible carbohydrates and/or polyols.

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