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# Comparative studies of gastrointestinal tolerance and acceptability of milk chocolate containing either sucrose, isomalt or sorbitol in healthy consumers and Type II diabetics

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## Vergleichende Untersuchungen über die gastrointestinale Verträglichkeit und Akzeptanz von Milchschokolade mit Saccharose, Isomalt oder Sorbit bei gesunden Normalverbrauchern und Typ-II-Diabetikern

*Summary:* The objective was to compare reaction of adult consumers of confectionery to milk chocolate made with either isomalt, sucrose or sorbitol. Test chocolate was eaten by subjects at home during 7 days in amounts chosen by them up to a maximum of 100 g per day. In a double-blind crossover trial isomalt chocolate was associated in healthy consumers (n = 58) with increased motion frequency, wind and flatulence compared with sucrose chocolate. However, the intensity of these gastrointestinal effects was predominantly slight and insufficient to affect acceptability. In separate crossover trials, reactions of Type II diabetic consumers to eating isomalt chocolate (n = 53) or sorbitol chocolate (n = 51) were compared to reactions when eating no chocolate. Both isomalt and sorbitol chocolate were associated with higher incidence of wind and flatulence than for no chocolate, but only sorbitol chocolate increased motion frequency. Again intensity of gastrointestinal effects was slight. It is concluded that isomalt has potential use in both regular and diabetic chocolate.

*Zusammenfassung:* Die Reaktionen von erwachsenen Verbrauchern bei Konsum von Süßwaren gegenüber Milchschokolade mit Isomalt, Saccharose oder Sorbit sollten verglichen werden. Die Teilnehmer aßen während 7 Tagen die Schokolade daheim in Mengen, die sie selbst gewählt hatten, wobei sie maximal 100 g pro Tag zu sich nehmen sollten. In einem Doppelblind-Crossover-Versuch stellten gesunde Teilnehmer nach dem Genuß von Isomaltschokolade höhere Stuhlhäufigkeit, Gasbildung und Blähungen fest im Vergleich zu Saccharoseschokolade. Die Intensität dieser Magen-Darm-Effekte war jedoch überwiegend gering und somit nicht ausreichend, um die Akzeptanz der Schokoladen in Frage zu stellen. In weiteren Crossover-Versuchen wurden die Reaktionen von Typ-II-Diabetikern auf Isomaltschokolade (n = 53) oder Sorbitolschokolade (n = 51) mit denen bei Verzicht auf Schokoladekonsum verglichen. Sowohl bei Isomalt- wie auch bei Sorbitschokolade wurden erhöhte Gasbildung und Flatulenz festgestellt; jedoch rief nur die Sorbitschokolade eine höhere Stuhlfrequenz hervor. Wiederum war die Intensität der Magen-Darm-Effekte unerheblich, woraus geschlossen wird, daß Isomalt für den Einsatz in normaler und Diabetikerschokolade geeignet ist.

*Key words:* isomalt, chocolate, gastrointestinal effect, acceptability

*Schlüsselwörter:* Isomalt, Schokolade, Magen-Darm-Effekte, Verträglichkeit

## Introduction

Sorbitol has a long-established place in diabetic confectionery, but associated gastrointestinal effects like wind and diarrhoea have limited its use. In some countries regulators insist on a label warning of laxative effects for foods containing sorbitol. More recently developed polyols, for example isomalt, maltitol and lactitol, have been permitted in food mainly because they are claimed to provoke less intense gastrointestinal effects. As they are also claimed to have superior sensory qualities, it is possible that they could become used in regular as well as diabetic foods. It is thus important that the claims of superiority be tested. The tests reported here aim to assess the validity of such claims in relation to isomalt.

Isomalt consists of an equimolar mixture of α-D-glucopyranosido-1,6-sorbitol and α-D-glucopyranosido-1,6-mannitol, made by hydrogenation of isomerised sucrose. Evidence published to date on the gastrointestinal effects of isomalt relating to dose effect (3), long term tolerance (10) and comparison with fructose, sucrose, glucose, and sorbitol (1, 9, 12) comes from clinical tests using small numbers of subjects. While such evidence is essential in assessing side effects of isomalt, it offers little guidance on the expected consequences of normal home consumption of confectionery in which sucrose or sorbitol has been replaced by isomalt. The tests reported here address this issue directly in relation to home consumption of milk chocolate containing isomalt by diabetic and non-diabetic consumers.

## Materials and Methods

*Treatments*

The three milk chocolate samples used have the nutritional compositions shown in Table 1. Samples I and II, containing sucrose and isomalt respectively, were made specifically for the tests by a chocolate manufacturer using traditional chocolate making technology, while sample III was a commercial diabetic milk chocoate containing sorbitol on sale in Austria. In Trial 1, a double blind crossover trial, samples I and II were presented in plain white wrappers bearing only the letters L and K respectively. In Trials 2 and 3, samples II and III were presented in commercial packaging bearing trade names.

*Test Populations*

In Trial 1 ninety-seven non-diabetic consumers aged 16–60 years were recruited from all regions of Austria such that there were equal numbers of men and women, with two thirds in the 16–39 years group and one third in the 40–60 years group. For

Table 1. Approximate nutritional content of chocolate samples.

| | | Sample I | Sample II | Sample III |
|---|---|---|---|---|
| Protein | % | 7 | 7 | 9 |
| Fat | % | 31 | 31 | 39 |
| Sucrose | % | 46 | – | – |
| Isomalt | % | – | 45 | – |
| Sorbitol | % | – | – | 25 |
| Fructose | % | – | – | 10 |
| Lactose | % | 10 | 10 | 10 |

both Trials 2 and 3 more than eighty Austrian non-insulin-dependent (Type II) diabetics were separately recruited such that there were approximately equal numbers of men and women with one third in the 16–39 years group and two thirds in the 40–60 years group.

All trial subjects were required to be regular consumers of chocolate, defined as eating at least 100 g of chocolate or chocolate-covered confectionery every two weeks. Potential subjects were excluded if they suffered from stomach ulcers, high cholesterol, allergy, diarrhoea, constipation or had experienced intestinal surgery. They were also excluded if they had in the previous four weeks taken antibiotics, steroids, antispasmodics, antiasthmatics or laxatives.

*Test Method*

The designs of the three Trials are shown in Figure 1, each was a crossover trial with two test periods of 7 days separated by a 3 days adaptation period. Only Trial 1 was double blind.

For the seven days test periods in Trial 1, subjects were given seven 100 g bars of either sample I or sample II chocolate. They were requested to eat as little or as much each day as they wished, up to a maximum of one complete bar. For the seven days test periods in Trial 2 and 3 subjects were given either no chocolate or three 100 g bars of either sample II or sample III. Instructions on chocolate consumption were the same as for Trial 1.

Amount and time of consumption of chocolate, other food intake and incidence and severity of gastrointestinal symptoms were among the data recorded each day in seventeen-day diaries by all subjects. Chocolate consumption was measured as the number of square pieces eaten, each 100 g bar containing 24 squares. Data were available as total amount of chocolate eaten per day and also as the maximum eaten in any one hour period of the day. Stomach ache, wind (passing of intestinal gas), flatulence (bloating sensation in abdomen), and cramp were rated on a 0–5 scale, where 0 represented no symptom, 1 and 2 a mild symptom, 3 a moderate symptom and 4 and 5 a strong symptom. The number of separate motions per day was recorded and stool consistency was classified as very hard, hard, normal, soft or watery. Tendency to diarrhoea was considered mild with 1, moderate with 2, and severe with 3 soft or watery motions per day.

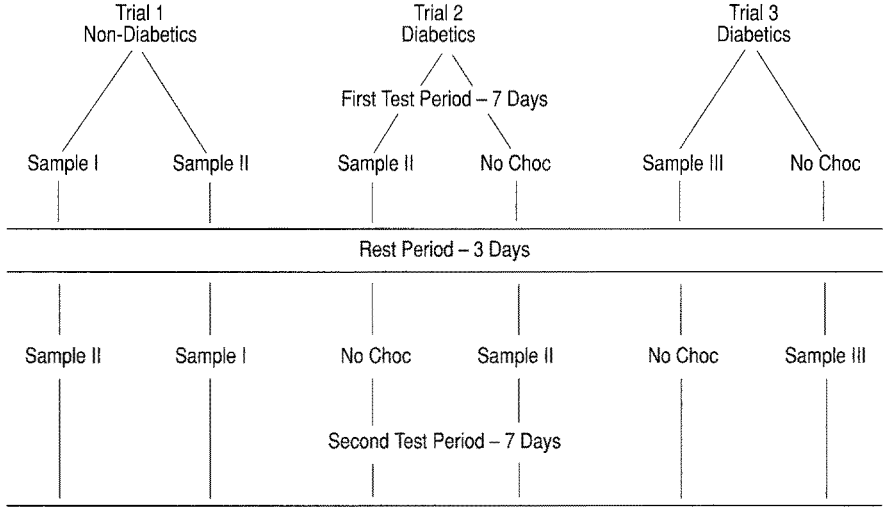


Fig. 1.

At the end of each test period subjects were asked to rate the acceptability of the test chocolate on a 1–5 scale, where 5 indicated very good and 1 not at all good. In Trial 1 after both products had been tested subjects were asked whether they preferred sample I or sample II.

*Data Analysis*

Chocolate consumption data were tested for difference between samples and age of subjects by analysis of variance.

Data on incidence of symptoms were separately analysed for the three trials. Two statistical procedures were used, the first utilised chi-square to compare the total incidences of a specific symptom experienced with each sample. The second compared the maximum severity of symptom experienced by each subject with each sample. These data were entered in a symmetric contingency table for each symptom and analysed by chi-square as modified by the procedure of Gart (4) and McNemar (8).

Differences in average motion frequency for each subject during the seven days test periods within each trial were analysed by paired t-tests.

## Results and Discussion

Nineteen out of 291 recruited subjects failed to complete the trials, of which 11 found it too time consuming, 4 complained of side effects, 3 went on holiday and 1 failed to eat the chocolate. The 4 who complained of side effects were diabetics of whom 3 were taking chocolate containing sorbitol and 1 was taking chocolate containing isomalt.

Of the 272 subjects completing the trials, 110 failed to observe the three days rest period. These non-complying subjects were spread evenly throughout the trials and age groups and their results have been excluded.

It is necessary when viewing the chocolate consumption data in Table 2 to note that Trial 1 cannot be compared with Trials 2 and 3. The non-diabetics in Trial 1 could eat 100 g chocolate per day, while Type II diabetics in Trials 2 and 3 were given just 300 g chocolate for 7 trial days permitting a maximum average daily consumption of only 43 g.

Two important aspects of chocolate consumption in Trial 1 arise from the data in Table 2. One is that the average amounts eaten of sample I and sample II are not significantly different, allowing a valid comparison of incidence of gastrointestinal effects. The second is the significantly larger ($P < 0.01$) chocolate consumption of 16–39 years group compared with 40–60 years group, both as total consumption and maximum one hour consumption. Inter-trial comparisons clearly need to take age of subjects into account.

In Trials 2 and 3, 36 % subjects ate all the isomalt chocolate and 25 % all the sorbitol chocolate. There was no difference in average consumption between different age groups in Trials 2 or 3. However owing to formulation differences the amount of isomalt consumed was about twice that of sorbitol. Combined data from these trials showed 16–39 year olds to have a higher average maximum one hour consumption of chocolate than 40–60 year olds. This may indicate that the lack of difference in average consumption was caused by the limited amount given to diabetics.

There was remarkable similarity in chocolate consumption profiles between diabetic and non-diabetic 40–60 year olds.

Table 2. Chocolate, sucrose and polyol consumption data.

| Trial no/ Treatment | Subjects | | Chocolate eaten | | Sugar/Polyol from chocolate | |
|---|---|---|---|---|---|---|
| | No | Age group | per day mean wt (g) | 1 hr max. | per day mean ± SD (g) | 1 hr max. |
| Trial 1 | | | | | | |
| Sample I | 43 | 16–39 | 60 | 51 | 27 ± 11 | 23 ± 13 |
| (Sucrose) | 15 | 40–60 | 37 | 32 | 17 ± 11 | 15 ± 11 |
| Sample II | 43 | 16–39 | 56 | 47 | 25 ± 11 | 21 ± 12 |
| (Isomalt) | 15 | 40–60 | 36 | 27 | 16 ± 10 | 12 ± 10 |
| Trial 2 | | | | | | |
| Sample II | 16 | 16–39 | 35 | 33 | 16 ± 10 | 15 ± 5 |
| (Isomalt) | 37 | 40–60 | 34 | 29 | 15 ± 9 | 13 ± 8 |
| Trial 3 | | | | | | |
| Sample III | 16 | 16–39 | 33 | 33 | 8 ± 5 | 8 ± 3 |
| (Sorbitol) | 35 | 40–60 | 30 | 24 | 8 ± 4 | 6 ± 3 |

Table 3. Relative occurrence of symptoms in diabetics and non-diabetics.

| | Non-diabetics | | | Diabetics | | | | |
|---|---|---|---|---|---|---|---|---|
| | Trial 1 (n = 58) | | | Trial 2 (n = 53) | | | Trial 3 (n = 51) | |
| Symptom/ Strength | Sample I | | Sample II | No Choc | | Sample II | No Choc | Sample III |
| | % test days | | | | | | | |
| **Stomach ache** | | | | | | | | |
| None | 94.3 | | 97.1 | 97.6 | | 96.5 | 96.6 | 96.6 |
| Slight | 5.7 | | 2.7 | 2.4 | | 3.0 | 3.1 | 3.1 |
| Moderate | – | | 0.2 | – | | – | 0.3 | 0.3 |
| Severe | – | | – | – | | 0.5 | – | – |
| **Flatulence** | | | | | | | | |
| None | 86.5 | ** | 80.0 | 86.3 | ** | 77.9 | 84.0 | ** 74.2 |
| Slight | 12.8 | | 17.0 | 12.7 | | 19.4 | 16.0 | 21.0 |
| Moderate | 0.7 | | 2.5 | 0.5 | | 1.4 | – | 2.8 |
| Severe | – | | 0.5 | 0.5 | | 1.3 | – | 2.0 |
| **Cramp** | | | | | | | | |
| None | 97.0 | | 95.8 | 96.7 | ** | 91.1 | 96.6 | 94.4 |
| Slight | 2.7 | | 3.2 | 2.7 | | 7.6 | 3.1 | 5.0 |
| Moderate | 0.3 | | 0.5 | 0.3 | | 0.5 | – | 0.6 |
| Severe | – | | 0.5 | 0.3 | | 0.8 | 0.3 | – |
| **Wind** | | | | | | | | |
| None | 67.5 | * | 58.9 | 59.3 | ** | 53.9 | 52.1 | ** 39.8 |
| Slight | 25.9 | | 32.0 | 38.3 | | 36.7 | 43.4 | 51.0 |
| Moderate | 5.4 | | 7.1 | 2.1 | | 5.9 | 4.5 | 5.6 |
| Severe | 1.2 | | 2.0 | 0.3 | | 3.5 | – | 3.6 |

*, ** Significant association between symptom and samples within trial at $p < 0.05$ and $p < 0.01$, respectively.

Table 4. Symptoms assessed as maximum subject responses.

| | Trial 1 | Trial 2 | Trial 3 |
|---|---|---|---|
| | Non-diabetic Sample I v Sample II | Diabetic Sample II v No choc | Diabetic Sample III v No choc |
| Symptoms | | Significance level | |
| Diarrhoea | 0.05 | n.s. | 0.05 |
| Flatulence | 0.05 | n.s. | 0.05 |
| Wind | * | n.s. | n.s. |
| Stomach ache | n.s. | n.s. | n.s. |
| Cramp | n.s. | n.s. | n.s. |

* Significant difference $p < 0.05$ for 16–39 year olds only.
n.s. no significant difference $p = 0.05$.

The amount of chocolate eaten each day was influenced by the geometry of the bar which consisted of $4 \times 6$ squares. The three most common amounts consumed were the whole bar, half bar and one third bar.

Relative occurrence of gastrointestinal symptoms in non-diabetics and Type II diabetics is shown in Table 3. Incidences of wind and flatulence were associated with isomalt and sorbitol chocolate alike. The strength of symptom was predominantly slight.

Analysis of subject maximum responses using contingency tables differentiated more clearly between the effects of isomalt and sorbitol chocolate in diabetics (Table 4). There were fewer statistically significant effects due partly to the reduced number of observations, but also because symptoms were not randomly dispersed among subjects. The majority of subjects seem to be tolerant of isomalt, but a few subjects experienced symptoms on most days.

The extent of laxative action of polyols is summarised in Table 5. Increased motion frequency was associated in non-diabetics with isomalt chocolate compared with sucrose chocolate. In diabetics, where the comparison was with no chocolate, sorbitol chocolate was associated with increased motion frequency but isomalt chocolate was not. Both these effects confirm the analysis of maximum response data in Table 4. Stool consistency data in Table 5 suggest that the effect of isomalt and sorbitol chocolate is not uniform, increases in hard, soft and watery stools being indicated.

Paired t-testing of differences in average motion frequency of subjects within Trials showed an increase in frequency of 0.13 motion/day in non-diabetics when eating isomalt chocolate compared with sucrose chocolate ($p < 0.01$). In diabetics, eating sorbitol chocolate resulted in an increased frequency of 0.12 motion/day compared with no chocolate ($p < 0.05$), but isomalt chocolate was without effect on motion frequency.

The fact that chocolate consumption was similar for 40–60 year olds whether diabetic or not provided an opportunity for comparing motion frequency in the two groups. In fact, the motion frequencies, 1.13 and 1.19 motions per day, are very similar. However, the variance of the diabetic

Table 5. Laxative effects in diabetics and non-diabetics.

| | Non-diabetics | | Diabetics | | | |
|---|---|---|---|---|---|---|
| | Trial 1 (n = 58) | | Trial 2 (n = 53) | | Trial 3 (n = 51) | |
| | Sample I | Sample II | No Choc | Sample II | No Choc | Sample III |
| *Motions per day* | | | | | | |
| | | | No of test days | | | |
| | | * | | | | ** |
| None | 35 | 29 | 45 | 37 | 41 | 25 |
| 1 | 257 | 232 | 218 | 225 | 213 | 205 |
| 2 | 99 | 117 | 94 | 100 | 92 | 114 |
| 3 | 15 | 25 | 10 | 8 | 9 | 11 |
| 4 | – | 3 | 4 | 1 | 2 | 2 |
| *Stool consistency* | | | | | | |
| | | | No of motions | | | |
| | | * | | ** | | ** |
| Watery | 2 | 8 | 1 | 12 | 1 | 10 |
| Soft | 42 | 51 | 47 | 36 | 34 | 20 |
| Normal | 379 | 375 | 347 | 337 | 320 | 315 |
| Hard | 73 | 110 | 57 | 66 | 76 | 116 |
| Very hard | 4 | 9 | 0 | 2 | 1 | 13 |
| Total | 500 | 553 | 452 | 453 | 432 | 474 |

*, **Significant association between laxative measure and samples within trial at $p < 0.05$ and $p < 0.01$, respectively.

data was four times that of the non-diabetic data. Thus if we were looking at incidence of extreme symptoms, data from non-diabetics could be seriously misleading if appied to diabetics.

Concerning acceptability of chocolate among non-diabetics, 19 preferred sample I, 19 preferred sample II, 15 preferred them equally and 6 could not decide. The increase in slight gastrointestinal symptoms arising from the presence of isomalt, rather than sucrose, in milk chocolate proved insufficient to affect the acceptability of isomalt chocolate by non-diabetic consumers. Among diabetics isomalt chocolate was rated significantly higher for acceptability than sorbitol chocolate.

The incidence of gastrointestinal effects in these trials may be compared with those in tolerance studies on sorbitol and isomalt. Despite variability of results in such studies there is agreement that an acute dose of more than 20 g sorbitol will normally lead to osmotic diarrhoea in adults, while the tolerance threshold is about 50–60 g for doses spaced throughout the day (2, 5, 6, 11). Tolerance data for isomalt are less well established, but comparative studies suggest that isomalt is marginally superior to sorbitol. One report (14) showed few gastrointestinal responses in healthy subjects from acute doses of isomalt or sorbitol at 10 g and 20 g doses but high instances of diarrhoea from both at 40 g with fewer from isomalt than sorbitol. Comparison of 50 g doses of isomalt and sorbitol in healthy

subjects taken in three protions during a day (13) showed similar flatulence with both but better tolerance of isomalt in relation to diarrhoea. Type II diabetics taking 50 g doses of isomalt and sorbitol over a three hour period (7) showed the same proportion, 8 out of 12, reporting gastrointestinal complaints.

The results presented in Tables 3, 4, and 5 show similar superiority of isomalt to sorbitol. The difference from earlier trials being that this superiority was demonstrated even though twice the amount of isomalt was eaten as sorbitol. Moreover, the symptoms were experienced with an average acute dose level of sorbitol of only 8 g.

In seeking an explanation for this we need to note that the level of symptoms in these trials was predominantly slight. Clinical trials seek to measure levels of symptoms that are clinically significant and involve smaller numbers of subjects and more quantitative measures than used in these trials. For example it would have been impossible to demonstrate statistically significant differences in these tests with the number of subjects normally used in clinical studies.

Other factors may have influenced the results such as the higher fat content of sorbitol chocolate and the possibility that diabetics, knowing that the chocolate contained sorbitol, over-reported symptoms. In practice, however, sorbitol chocolate usually contains a high level of fat for technological reasons and consumers would normally be aware of the presence of sorbitol in chocolate form the pack copy.

In relation to the use of isomalt and sorbitol in chocolate the evidence in general suggests that isomalt is a satisfactory substitute for sucrose in regular milk chocolate and offers clear advantages over sorbitol in diabetic chocolate.

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