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Note

The Maximum Single Dose of Resistant Maltodextrin That Does Not Cause Diarrhea in Humans

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Summary The objective of the present study was to determine the maximum dose of resistant maltodextrin (Fibersol®-2, a non-viscous water-soluble dietary fiber), that does not induce transitory diarrhea. Ten healthy adult subjects (5 men and 5 women) ingested Fibersol®-2 at increasing dose levels of 0.7, 0.8, 0.9, 1.0, and 1.1 g/kg body weight (bw). Each administration was separated from the previous dose by an interval of 1 wk. The highest dose level that did not cause diarrhea in any subject was regarded as the maximum non-effective level for a single dose. The results showed that no subject of either sex experienced diarrhea at dose levels of 0.7, 0.8, 0.9, or 1.0 g/kg bw. At the highest dose level of 1.1 g/kg bw, no female subject experienced diarrhea, whereas 1 male subject developed diarrhea with muddy stools 2 h after ingestion of the test substance. Consequently, the maximum non-effective level for a single dose of the resistant maltodextrin Fibersol®-2 is 1.0 g/kg bw for men and >1.1 g/kg bw for women. Gastrointestinal symptoms were gurgling sounds in 4 subjects (7 events) and flatus in 5 subjects (9 events), although no association with dose level was observed. These symptoms were mild and transient and resolved without treatment.

Key Words resistant maltodextrin, soluble dietary fiber, non-effective dose level, diarrhea, tolerance

Indigestible carbohydrates such as dietary fiber, oligosaccharides, and sugar alcohol are known to have beneficial physiological effects in humans, and because such compounds have low energy values, they have been used in many functional and/or low-calorie food and beverage products. However, attention must be given to the quantities included in foods because indigestible carbohydrates generally reach the large intestine undigested and unabsorbed, and may elevate osmotic pressure and induce osmotic diarrhea (*1*, *2*). It is important to determine the maximum non-effective level for a single dose (i.e., the maximum dose that does not cause diarrhea) of indigestible carbohydrates. This is especially true for oligosaccharides and sugar alcohols (polyols) used in foods, because these compounds have lower molecular weights and therefore increase the osmotic pressure in the digestive tract. Therefore, maximum non-effective levels have been investigated and determined separately for each substance (*3*, *4*).

Meanwhile, although dietary fibers are also indigestible carbohydrates, few studies have reported diarrhea caused by these substances. Dietary fibers are not believed to cause diarrhea for the following reasons: (1) dietary fibers occur naturally in vegetables, fruits, grains, and seaweeds, and have relatively high molecular weights and are therefore unlikely to affect osmotic pressure in the digestive tract, and (2) most dietary fibers have the physical property of moisture retention.

In recent years, however, various low-molecular-weight water-soluble dietary fibers have been developed for use in healthy food and beverage products. Resistant maltodextrin, polydextrose, and inulin are representative examples of low-molecular-weight soluble dietary fibers that may induce gastrointestinal symptoms, including osmotic diarrhea, similar to oligosaccharides (*5*). Studies have investigated the effects of low-molecular-weight soluble dietary fibers on gastrointestinal symptoms, and one study reported that a 5–10 g single dose of inulin caused abdominal flatulence in 42–50% of subjects, and diarrhea in some cases (*6*).

Fibersol®-2, a resistant maltodextrin, has never been reported to induce severe gastrointestinal symptoms or diarrhea, suggesting that such side effects are of no clinical concern for this product. Repeated administration in human subjects showed that no diarrhea was induced by the continuous intake of 60 g/d (20 g 3-times daily) for 3 mo (*7*). Another study of the acute effects of excessive intake found no cases of diarrhea with single doses of 50 g (*8*). To date, however, no study has investigated the maximum non-effective dose of Fibersol®-2 (i.e., the maximum single dose that does not cause diarrhea in any subject). There is the possibility of simultaneously consuming more than one food product containing resistant maltodextrin, because the compound has been

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Table 1. Exclusion criteria.

1. Person with any history of gastrointestinal desease in the past
2. Person whose fecal condition is usually muddy or watery
3. Person taking medication or drugs
4. Person who has a serious disease or had any history of diseases related to liver, kidney, heart, lung, blood, digestive system, endocrine system, exocrine system, etc.
5. Person who has extremely irregular and improper lifestyle and/or dietary habits
6. Person who is a heavy user of alcohol[1]
7. Person who is determined as inadequate due to an abnormal result during the screening process
8. Person with an allergy to any food or medical substance
9. Person who is in another clinical trial
10. Person who is determined as inadequate by the doctor in charge of the study due to other reasons

[1] Definition of 'heavy user of alcohol' is based on "National Health and Nutrition Survey" of Japan. One unit of an alcoholic drink is 180-mL rice wine, which is equivalent to 500-mL beer.
1) Person who consumes 5 units or more per day.
2) Person who consumes between 4 and less than 5 units per day on 5 or more days weekly.
3) Person who consumes between 3 and less than 4 units every day.

Table 2. Characteristics of the subjects.

	Total (n=10)	Male (n=5)	Female (n=5)
Age (y old)	40.8±9.5	40.0±10.6	41.6±9.4
Height (cm)	163.3±8.2	169.0±7.0	157.5±4.4
Body weight (kg)	55.3±5.8	57.3±4.6	53.3±6.6
BMI	20.8±0.02	20.1±0.02	21.5±0.02
Systolic blood pressure	109.3±14.2	110.0±4.4	108.8±18.5
Diastolic blood pressure	68.0±7.6	69.3±0.6	67.2±9.9
AST (GOT)	17.5±2.5	16.2±1.6	18.8±2.6
ALT (GPT)	15.1±5.4	13.4±4.0	16.8±6.5
γ-GTP	28.2±24.9	21.0±9.8	35.4±34.1
CPK	89.3±21.0	93.6±23.5	85.0±19.8
Total cholesterol	198.3±42.6	188.4±28.2	208.2±55.1
Triglycerol	70.8±41.2	71.6±27.3	70.0±55.5
HDL-cholesterol	75.4±12.8	72.8±6.2	78.0±17.7
LDL-cholesterol	107.4±32.5	101.4±26.1	113.4±40.1
Uric acid	4.9±1.0	5.4±0.7	4.3±0.9
BUN	13.1±3.6	14.2±4.2	12.1±3.0
Creatine	0.8±0.1	0.9±0.1	0.7±0.1
Fasting blood glucose	86.0±6.9	89.6±8.0	82.4±3.4
Hemoglobin A1c	4.9±0.4	5.0±0.3	4.9±0.4
Red blood cells	462.2±47.1	490.4±27.8	434.0±47.2
Hemoglobin	13.9±1.2	14.9±0.4	12.8±0.6
Hematocrit	42.8±3.8	46.1±0.8	39.4±2.1

Means±SD.

incorporated in various foods and beverages, including those categorized as Food for Specified Health Uses (FOSHU) products. Therefore, the present study was conducted to identify the maximum non-effective level of a single dose of resistant maltodextrin (Fibersol®-2); i.e., the highest single oral dose at which no participant experienced diarrhea.

Materials and Methods

Test substance. The test substance was resistant maltodextrin (Fibersol®-2, Matsutani Chemical Industry Co., Ltd., Hyogo, Japan) derived from cornstarch (*9*). Fibersol®-2 is a non-viscous water-soluble dietary fiber, and the dietary fiber content was analyzed as 93.7% by AOAC 2001.03, an enzymatic high-performance liquid chromatography method.

Subjects. The protocol was approved in advance by the institutional review board of Chiyoda Paramedical Care Clinic (CPCC) in December 2010, and the study was conducted by CPCC Co., Ltd. (Tokyo, Japan) in accordance with the spirit of the Declaration of Helsinki and the Ethical Guidelines for Epidemiological Research of Japan. Subjects were Japanese male and female volunteers aged between 20 and 65 y, who did not meet

Table 3. The dose ranges of Fibersol®-2, resistant maltodextrin, actually ingested by the subjects at each level.

Subjects	Ranges of a single dose (g: minimum–maximum)				
	0.7 g/kg bw	0.8 g/kg bw	0.9 g/kg bw	1.0 g/kg bw	1.1 g/kg bw
Male (n=5)	36.61–44.73	41.84–51.12	47.07–57.51	52.30–63.90	57.53–70.29
Female (n=5)	32.48–43.26	41.84–49.44	41.76–55.62	46.40–61.80	51.04–67.98

bw, body weight.

any of the exclusion criteria shown in Table 1. Each volunteer was fully informed in advance about the study design, including the objectives, methods, and anticipated adverse symptoms. Ten healthy adults (5 male and 5 female subjects) provided written consent and were evaluated in the study. The characteristics of the subjects are shown in Table 2.

Oral single-dose study. The experimental design was based on the method of Oku (*3*) and Nakamura (*4*). Subjects repeatedly ingested the test substance orally beginning at the lowest dose and progressing to the higher doses with a 1-wk washout period between administrations. The highest dose that did not cause diarrhea in any subject was defined as the maximum non-effective dose. All subjects ingested a single dose of the test substance at increasing dose levels of 0.7, 0.8, 0.9, 1.0, and 1.1 g/kg body weight (bw). Fibersol®-2 was weighed according to the body weight of each subject and dissolved in warm water up to a total volume of approximately 200 mL. Each test solution was ingested after breakfast at approximately 10 AM on a non-working day. The dose ranges actually ingested by the subjects based on body weight at each level are shown in Table 3. Subjects were asked to complete a questionnaire on stool condition and gastrointestinal symptoms experienced during the week before and after each dose. The stool condition was subjectively rated on a 6-level stool scale: 1) Very hard (pellet-shaped); 2) Hard-solid; 3) Normal (banana-shaped); 4) Soft pastry; 5) Very soft (muddy); and 6) Watery. Muddy stool and watery stool were regarded as diarrhea. The protocol required that if a subject developed diarrhea before reaching the highest dose level, administration should be discontinued. During the study period, subjects were instructed to abstain from foods rich in dietary fiber and from dairy products such as yogurt, and to avoid overeating, while maintaining their lifestyles as normal (although they were instructed to abstain from excessive exercise). Subjects were asked to record on a survey form all foods and beverages consumed during the 2 d before dosing and on the day of the dosing. Drinking alcohol was prohibited on the day before each ingestion. If subjects were taking medical products, they were required to inform the researchers and obtain prior permission to use the medication from the principal investigator, except in emergency situations, and they were required to record the name of and the reason for taking each medicine, and the date and amount taken.

Table 4. Effect of Fibersol®-2, resistant maltodextrin, on stool conditions in humans (number of subjects).

Stool scale	Subject	Single dose level (g/kg bw)				
		0.7	0.8	0.9	1.0	1.1
1 Very hard (Pellet-shaped)	Male (n=5)	1	1	1	0	1
	Female (n=5)	0	0	0	0	0
	Total (n=10)	1	1	1	0	1
2 Hard solid	Male (n=5)	0	0	0	0	0
	Female (n=5)	2	1	1	1	2
	Total (n=10)	2	1	1	1	2
3 Normal (Banana-shaped)	Male (n=5)	2	4	3	5	3
	Female (n=5)	2	3	3	2	2
	Total (n=10)	4	7	6	7	5
4 Soft pastry	Male (n=5)	2	0	1	0	0
	Female (n=5)	1	1	1	2	1
	Total (n=10)	3	1	2	2	1
5 Very soft (Muddy)	Male (n=5)	0	0	0	0	1
	Female (n=5)	0	0	0	0	0
	Total (n=10)	0	0	0	0	1
6 Watery	Male (n=5)	0	0	0	0	0
	Female (n=5)	0	0	0	0	0
	Total (n=10)	0	0	0	0	0

Results

The average stool condition during the week before the first ingestion of the test substance was between hard-solid and soft pastry, and the average number of bowel movements was 6.2/wk (range 3–9/wk). No gastrointestinal symptoms were reported. The stool conditions reported after ingestion at each dose level are shown in Table 4. No subject of either sex experienced diarrhea at dose levels from 0.7 to 1.0 g/kg bw, and the average stool condition was between pellet-shaped and soft pasty. At the dose level of 1.1 g/kg bw, no female subject experienced diarrhea, whereas 1 male subject had muddy stools 2 h after ingestion, which was regarded as diarrhea. In this case, diarrhea was transient, and the subject's stools returned to normal on the following day. The results of the present study suggest that the maximum non-effective level for a single dose

Table 5. The gastrointestinal symptoms observed at different single dose levels of Fibersol®-2, resistant maltodextrin.

	Single dose level (g/kg bw)									
	0.7		0.8		0.9		1.0		1.1	
	Male (n=5)	Female (n=5)	Male (n=5)	Female (n=5)	Male (n=5)	Female (n=5)	Male (n=5)	Female (n=5)	Male (n=5)	Female (n=5)
Number of subjects with no side effects	5	3	4	2	4	4	4	5	3	3
Number of subjects with gastrointestinal symptoms	0	2	1	3	1	1	1	0	2	2
Rate of subjects with gastrointestinal symptoms (%)	0	40	20	60	20	20	20	0	40	40
Gastrointestinal symptoms										
Stomachache	0	0	0	0	0	0	0	0	0	0
Tenesmus	0	0	0	0	0	0	0	0	0	0
Gurgling sound	0	2	0	1	1	0	1	0	1	1
Flatus	0	1	1	2	0	1	0	0	2	2
Bloating/distention	0	0	0	0	0	0	0	0	0	0
Vomiting/nausea	0	0	0	0	0	0	0	0	0	0
Total number of symptoms	0	3	1	3	1	1	1	0	3	3

of Fibersol®-2 is 1.0 g/kg bw for men and >1.1 g/kg bw for women. Accordingly, the maximum actual single intake of Fibersol®-2 ranged from approximately 52 to 64 g for men and from 51 to 68 g for women.

Table 5 summarizes the gastrointestinal symptoms observed at different dose levels throughout the study. Across the dose levels (0.7–1.1 g/kg bw), 4 subjects reported gurgling sounds (2 men and 2 women; 7 events), and 5 subjects reported flatus (2 men and 3 women; 9 events). The incidence of these gastrointestinal symptoms was not associated with dose level. All the symptoms were mild and transient, and resolved without any medical treatment.

No subject used a medical product during the study period. There was no unusual food intake reported that could have affected gastrointestinal symptoms; only common foods were reported to have been consumed.

Discussion

The present study was conducted to determine the maximum non-effective level for a single dose of Fibersol®-2, a non-viscous water-soluble dietary fiber. When ingested at dose levels between 0.7 and 1.0 g/kg bw, Fibersol®-2 did not cause diarrhea in either male or female subjects. At the highest dose level (1.1 g/kg bw), 1 male subject developed transitory diarrhea; however, no female subject reported diarrhea at that dose level. Therefore, the maximum non-effective level for a single dose of Fibersol®-2 was estimated to be 1.0 g/kg bw for men and >1.1 g/kg bw for women. Further investigation with a placebo control to avoid psychological effects, and studies with a greater number of subjects, should be conducted to confirm the repeatability of our results, particularly given that the current study was small and the that sensitivity to diarrhea varies greatly between individuals.

The maximum non-effective dose of Fibersol®-2 is higher than that reported for other low-digestible saccharides (e.g., polyols). Maximum non-effective doses for monosaccharides (sorbitol, xylitol, and tagatose) have ranged from 0.15–0.42 g/kg bw, for disaccharides (maltitol, lactitol, palatinit, cellobiose, and lactulose) from 0.25–0.36 g/kg bw, and for oligosaccharides (galactooligosaccharide, fructooligosaccharide, and xylooligosaccharide) from 0.14–0.4 g/kg bw (*3*, *4*). The risk of osmotic diarrhea is strongly associated with the molecular weight of the substance ingested. Fibersol®-2 contains a mixture of oligosaccharides and polysaccharides, and its mean molecular weight is approximately 2,000 Da (*10*), which is higher than that of oligosaccharides. This could explain why diarrhea is less likely to occur after ingestion of Fibersol®-2. We previously studied branched corn syrup solid (BCS; containing 45% dietary fiber), which has a lower molecular weight (mean molecular weight 500 Da). The maximum non-effective dose of BCS (the dietary fiber fraction), determined using a similar method to that of the present study, was 0.5 g/kg bw for men and >0.6 g/kg bw for women (*11*). In the present study, the maximum non-effective level for a single dose of the dietary fiber fraction can be calculated to be 0.9 g/kg bw for men and >1.0 g/kg bw for women based on the dietary fiber content of Fibersol®-2 (93.7%). Both Fibersol®-2 and BCS are glucose polymers derived from starch, and the structures of each compound and their respective saccharide compositions are almost the same; however, their molecular weights differ substantially. When we compare the maximum non-effective doses of these 2 compounds, the higher maximum non-effective dose of Fibersol®-2 may be due to its high molecular weight.

The risk of osmotic diarrhea is not only associated with a compound's molecular weight, but also with its degradation by intestinal microflora. Substances that are easily degraded by intestinal microflora are quickly eliminated from the digestive tract, and are less likely to induce diarrhea (*12*). It has been reported that Fibersol®-2 is fermented by intestinal microflora such as *Bifidobacterium* (*13*). This property could also explain why Fibersol®-2 is less likely to induce diarrhea.

A review of the clinical tolerability of polydextrose (containing 75% dietary fiber; mean molecular weight 2,000 Da) concluded that the mean laxative threshold was 0.7 g/kg bw when given as a single dose (*14*); this figure is the dose at which half of the participants first experienced diarrhea. In the present study, 0.7 g/kg bw was set as the starting dose, and no subject experienced diarrhea up to 1.0 g/kg bw, indicating that polydextrose induces diarrhea at relatively lower doses than Fibersol®-2. The molecular weight of polydextrose is actually lower than that of Fibersol®-2 when measured using comparable methodology. Furthermore, the energy value for the dietary fiber fraction of polydextrose is regarded as 0 kcal/g, indicating that polydextrose is not fermented by intestinal microflora. These differences in physical properties between polydextrose and Fibersol®-2 probably affect their relative laxative thresholds. NUTRIOSE FB (wheat dextrin containing 53% dietary fiber; mean molecular weight 2,480 Da) is produced from starch, as is Fibersol®-2, and it has been reported that the maximum dose that does not cause diarrhea is 80 g/d (when the dose is split and given 4 times per day) (*15*). This means that a single 20 g dose did not induce diarrhea, although comparisons with our present results using Fibersol®-2 cannot be directly made due to the methodological differences between the studies. Promitor 70 (corn dextrin containing 70% dietary fiber; mean molecular weight 1,600 Da) did not induce diarrhea at a single dose of 25 g, but did cause gastrointestinal symptoms in slightly less than 50% of subjects (*16*). This suggests that the development of gastrointestinal symptoms varies depending on the physical properties of each substance such as dietary fiber content and molecular weight, even when the substances are in the same category of low-molecular-weight soluble dietary fiber. In comparison with other low-molecular-weight soluble dietary fibers, it appears that Fibersol®-2 is associated with a lower risk of diarrhea in spite of its very high dietary fiber content of 90%. The remaining portion of each product besides dietary fiber is digested and absorbed as glucose in the small intestine, and won't reach the large intestine nor affect the gastrointestinal symptoms.

The gastrointestinal symptoms observed after ingestion of Fibersol®-2 were gurgling sounds and flatus. It has been confirmed that Fibersol®-2 is fermented by intestinal microflora such as *Bifidobacterium* to generate hydrogen gas and short-chain fatty acids (*17*, *18*). The fermentation of Fibersol®-2 also occurred more slowly, compared to oligosaccharides, and approximately half of that reaching the large intestine was fermented (*19*). In contrast, it has been reported that almost all inulin was rapidly fermented and tended to generate more gas, and a 5–10 g single dose of inulin resulted in the gastrointestinal symptoms of gas/bloating and gurgling in 46% and 29% of subjects, respectively. Therefore, it is likely that the hydrogen gas and short-chain fatty acids generated after excessive ingestion of Fibersol®-2 caused the flatus although its fermentation pattern suggests that it will hardly induce gastrointestinal symptoms such as bloating with the normal amount of intake. The gurgling sounds may have been caused by bowel peristalsis stimulated by short-chain fatty acids. These symptoms are commonly observed following the ingestion of indigestible and fermentable substances. The gastrointestinal symptoms reported in the present study were transient and resolved without any medical treatment, suggesting that they are of low clinical relevance.

A typical amount of Fibersol®-2 incorporated in commercially available fiber-enriched foods or FOSHU in Japan is approximately 5 g/serving. Even if these foods are consumed excessively, or multiple foods containing Fibersol®-2 are consumed together, the total amount is unlikely to exceed the maximum non-effective dose (e.g., 50 g for adults weighing 50 kg). Consequently, the risk of diarrhea after ingestion of Fibersol®-2 would be low in people with normal dietary habits.

Conclusion

Ten subjects (including men and women) ingested Fibersol®-2, a resistant maltodextrin fiber, at increasing dose levels of 0.7, 0.8, 0.9, 1.0, and 1.1 g/kg bw with a 1-wk interval between administrations. The maximum single dose of Fibersol®-2 that did not cause diarrhea was 1.0 g/kg bw for men and >1.1 g/kg bw for women. Gastrointestinal symptoms such as gurgling sounds were reported by 4 subjects and flatus was reported by 5 subjects throughout the study; however, these symptoms were mild and transient, and resolved without treatment.

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