

**Estimation of Maximum No-effect Dose of Xylitol
in Causing Diarrhea in Humans**

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Naoko Koizumi ^{a)}, Ruriko Ninomiya ^{a)}, and Masami Fujii ^{b)}

a) Department of Public Health, Hyogo College of Medicine

b) Faculty of Pharmacy Science, Kobe Gakuin University

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Abstract

Recently, health consciousness has developed with increased incidence of life-style related diseases. In particular, hyperlipidemia due to high caloric intake accounts for about 20 percent of workers and the development of sweeteners which do not elevate blood sugar levels has been awaited. However, sugar alcohol is known to have a laxative effect as a physiological effect on the human body. This should be kept in mind in applying to food.

Since xylitol, which is currently mixed in a variety of food products, also has a laxative effect, this study was conducted to estimate its maximum no-laxative oral dose for the purpose of ensuring safety in humans. A total of 40 subjects in their twenties to fifties, 5 males and 5 females in each decade, were studied. Single oral doses of xylitol were administered to investigate the appearance of diarrheal symptoms.

- 1) The maximum no-effect dose of xylitol in causing diarrhea when given once daily was estimated to be 0.3g/kg body weight in both males and females. The daily maximum no-effect dose calculated on the basis of average body weight of each 20 subjects was 20.8g in males and 15.8g in females. (Figure)
- 2) The dose to cause diarrhea in 50% of subjects (50% effective dose, ED50) was 0.52g/kg in males and 0.70g/kg in females and, on the basis of average body weight of each 20 subjects, 36.1g/day in males and 36.9g/day in females.
- 3) The time to the onset of diarrhea after ingestion was 2 to 3 hours and the time to return to normal abdominal condition was 10-12 hours. No significant differences in these time intervals were found between sexes.
- 4) Main abdominal symptoms associated with ingestion of xylitol were borborygmus, lower abdominal pain and nausea.

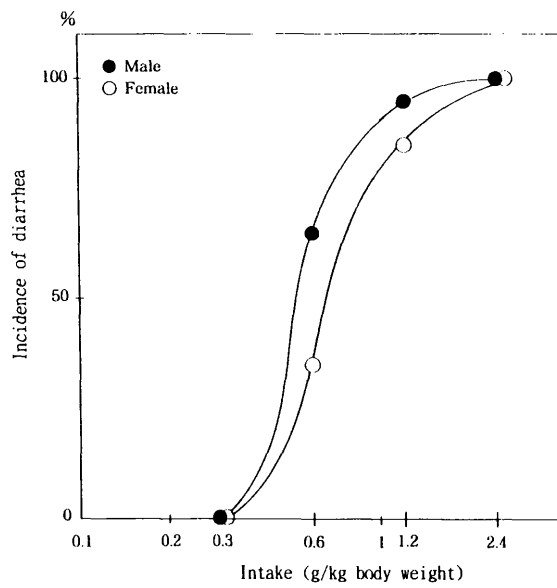


Fig. Dose-response relationship after oral ingestion of xylitol

Corresponding author:

Naoko Koizumi, Dept of Public Health, Hyogo College of Medicine,
1-1 Mukogawa-cho, Nishinomiya city, Hyogo 663-8501, Japan