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Original article

Effects of 4-week continuous ingestion of champignon extract on halitosis and body and fecal odor

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ABSTRACT

This was placebo-controlled double-blind parallel-group comparative clinical trial targeting 80 men and women aged 50–79 years with halitosis and body and fecal odor. We investigated whether daily champignon extract ingestion for 4 weeks improved these conditions. Subjects were divided into four groups: a placebo group and 50, 500, and 1000 mg/day ingestion groups. No severe adverse events or side effects were noted during the study period. Compared with the placebo group, all champignon extract ingestion groups showed improvement or tendency toward improvement in halitosis and body and fecal odor. Furthermore, our results suggested that the effectiveness of champignon extract in alleviating odors is dose-dependent, i.e., it increases with the dosage.

1. Introduction

Kareishu (literally, distinctive body odor of the middle-aged or elderly), which is believed to frequently occur in men aged ≥40 years,[1] is considered to be more common in modern society because of high animal fat-containing modern diets and high levels of stress. Halitosis and body and fecal odor negatively affect peoples' quality of life, and they are increasingly becoming a serious problem in caregiving settings in Japan, with the rapidly increasing proportion of the elderly in the Japanese society.

To manufacture champignon extract, an extract boiled from the mushroom *Agaricus bisporus* (*tsukuritake* or champignon mushroom) is mixed with dextrin and then spray-dried it into a powder. The extract contains amino acids, polyphenols, polysaccharides, flavonoids, vitamins, and minerals. Currently, this extract has been patented and is available for sale in Japan, six European countries, South Korea, the United States, and Canada. The most significant feature of champignon extract is deodorization within the intestinal tract.

Conditions such as halitosis and body and fecal odor are believed to be caused by certain toxic substances produced within the intestinal tract; champignon extract directly inhibits their production. Thus, champignon extract is widely used in candy, jellies, drinks, and other food products for maintaining both personal esthetics and health. Champignon extract shows a deodorizing effect by inhibiting ammonia nitrogen generation.[2] Furthermore, in an *in vitro* trial using gas chromatography to investigate its effects on the methyl mercaptan component of halitosis, champignon extract was found to increase the molecular weight of methyl mercaptan, thereby inhibiting its odor and causing overall decreased odor. This was because it converts the mercapto group of methyl mercaptan to sulfo group. Studies regarding the function of champignon extract and the utility of its characteristic effects against methyl mercaptan are underway.[2]

In a clinical trial targeting elderly inpatients (70 subjects; mean age: males 73.5 years, females 78.6 years) and involving ingestion of 2 g of champignon extract daily for 30 days, the extract was shown to not affect gastrointestinal symptoms but improved stool characteristics, reduced fecal and body odor, and decreased blood ammonia content. In another trial involving 24 residents of an elderly care facility who ingested jelly candies containing 300 mg of champignon extract daily for 30 days, favorable effects such as improved “stool characteristics” and “life satisfaction” were observed.

Here we aimed to investigate whether daily champignon extract ingestion for 4 weeks improved halitosis and body and fecal odor.

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2. Material and methods

2.1. Study design

We included 80 men and women aged 50–79 years with problematic halitosis and body and fecal odor in this placebo-controlled double-blind parallel-group comparative study. It involved four study groups: consisting of 3 test foods and a placebo, as shown in Table 1. (1) a placebo group ($n = 20$), (2) 50 mg/day champignon ingestion group ($n = 20$), (3) 500 mg/day champignon ingestion group ($n = 20$), and (4) 1000 mg/day champignon ingestion group ($n = 20$). The ingestion period was 4 weeks. With regard to ingestion volume and ingestion method, the test food was ingested as one packet (2 g) per day. However, we did not implement any restrictions regarding method or frequency of ingestion. The Champignon Extract BX100FPD (Ricom Corporation, Tokyo, Japan) used for ingestion.

Each subject underwent a medical interview and blood test on the day of starting ingestion of the test food and after 2 and 4 weeks of ingestion. The week before starting ingestion was set as the pre-observation period (washout period).

2.2. Study procedure

This study was approved by the Bioethics Committee of Hokkaido Information University. After providing the subjects with written and oral explanations of the study contents in accordance with the Declaration of Helsinki, we obtained written consent to participate from the subjects. After initially screening, this study included 80 consenting subjects, who fulfilled the selection criteria and not the exclusion criteria, and were believed to be suitable to participate by the principal investigator. For group allocation, an allocation manager from a third-party data center (Media Education Center, Hokkaido Institute of Information Technology, Ebetsu, Hokkaido) referred to the subject list and equally divided the subjects via stratified randomization into four groups considering age composition, male-to-female ratio, and odor questionnaire scores. The allocation manager carefully stored the allocation-related documents containing personal information of the subjects in a locked cabinet. Subjects were then notified of the date, time, and place for the clinical trial. Because three subjects quit the study owing to personal reasons before the trial started, only 77 subjects were finally included.

Subjects ingested one packet (2 g) per day of test food or placebo for 4 weeks from the day of starting ingestion. Subjects arrived at the assigned facilities on the day of starting ingestion and after 2 and 4 weeks of ingestion and underwent testing regarding prescribed items. The tests were conducted at the Health Center, Hokkaido Information University, Ebetsu Internal Medicine Clinic, Takahashi Internal Medicine 3Ban-dori Clinic, and Taguchi Clinic (all in Ebetsu, Hokkaido). Subjects began recording information in their lifestyle journals (daily condition, whether the test food was ingested, etc.) and also documented their bowel movements 1 week before starting ingestion and then throughout the 4-week study period until the completion of stool sampling. The journals were submitted on each clinic day and every time feces were sampled.

For disclosure (display of allocation list), when all relevant test results and analysis data had been prepared, the allocation manager displayed the subject allocation list. The ingestion rate was calculated with the following formula: Ingestion rate (%) = (number of test foods actually ingested/number of test foods planned to be ingested) × 100.

2.3. Ethics committee

All subjects provided written informed consent before undergoing any study-related tests, and the study protocol was approved by the Ethics Committee of Hokkaido Information University (a certificate number; 2014-04). The study protocol conformed to the Helsinki Declaration and was registered at the UMIN Clinical Trial Registration System (certificate number UMIN000014256).

2.4. Statistical analysis

The Wilcoxon rank sum test was used for intragroup comparisons and the Mann–Whitney U and chi-square tests were used for intergroup comparisons.

2.5. Study items

2.5.1. Visual analogue scale (VAS) questionnaire

For VAS questionnaire, 100-mm lines were prepared for each item with the left and right edges indicating worst and best states, respectively. We evaluated how subjects felt about their own state at the time of the questionnaire by having them mark an “X” on the relevant part of each line. The questionnaire results were scaled by measuring the length from the left edge to the “X” mark.

Subjects and cooperating people (those living along with the subjects) were asked to answer the questionnaire regarding halitosis and body and fecal odor using the prescribed method. Subjects were instructed to bathe and brush their teeth the night before and sleep using a clean pillow cover (or to cover the pillow with a towel) while wearing freshly laundered pajamas. The cooperating person evaluated halitosis after standing one handbreadth away from the subject and speaking to the subject for 1–2 min. For body odor evaluation, the odor of the pillow cover (or towel) and pajamas was evaluated by the subject and cooperating person.

For the questionnaire items regarding bowel movements, subjects evaluated the bowel movement status during the days between two clinic visits. However, if subjects could not record results at the time of awakening on the test day, they were allowed to include results from up to 2 days before the test day. We investigated the following four items: (1) fecal odor, (2) bowel movement

Table 1
Composition of placebo and test food materials.

Composition of materials	Quantity contained (mg)			
	Placebo	Test food		
		50 mg/day champignon	500 mg/day champignon	1000 mg/day champignon
Champignon extract BX100FPD	0	50	500	1000.00
Dextrin	1503.5	1458.1	1050.1	596.7
Glucose	400	400	400	400
Malic acid	90	85.5	45	0
Caramel (food color)	6.5	6.4	4.9	3.3

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