

# Acceleration of small bowel motility after oral administration of dai-kenchu-to (TJ-100) assessed by cine magnetic resonance imaging

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# **Abstract**

Ten healthy male volunteers took 5 g dose of either TJ-100 or lactose without knowing the identity of the substance. Each volunteer underwent two MR examinations after taking the other substance (TJ-100 or lactose) on separate days; they drank 1200 mL tap water and underwent cine MR examinations after 10 min. A steady-state free precession sequence was used for imaging, which was performed three times at 0, 10, 20, 30, 40, and 50 min. Bowel contraction frequency and distention score were assessed. Wilcoxon signed-rank test was used, and differences were considered significant for P values < 0.05.

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## **Protocol**

# Volunteers

# Step 1.

Ten healthy men (mean age, 39.1 [range, 25–53] years; mean body mass index, 23.2 [range, 20.3–26.7] kg/m²) were enrolled. The exclusion criteria were presence of ongoing gastrointestinal disease, history of abdominal surgery, and contraindications to MRI examination.

# Administration of dai-kenchu-to (TJ-100)

#### Step 2.

The volunteers fasted for 6 h without fluid intake for 2 h and were then administered TJ-100 (dai-kenchu-to, Tsumura, Tokyo, Japan) or lactose (lactose "Hoei," Pfizer, Tokyo, Japan) at a dose of 5 g wrapped in a wafer, with eyes closed in order to block visual and gustatory information. A controller not involved in the evaluation of cine MRI prepared TJ-100 and lactose for the double-blind test.

## Oral contrast agent

# Step 3.

After 20 min, the volunteers drank 1200 mL of tap water to distend the small bowel and underwent

MRI examinations. Each volunteer underwent two MRI examinations on separate days, and in the second examination, the other substance was administered (TJ-100 or lactose) after preparation as mentioned above. The interval between the two examinations was  $\geq 1$  week.

#### MRI examination

# Step 4.

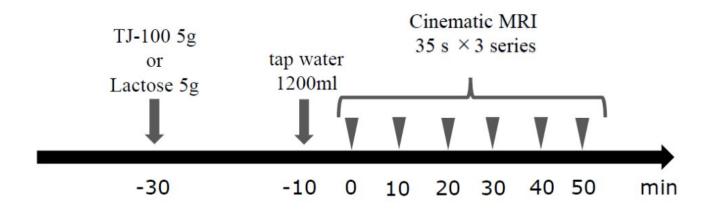
MRI examinations were performed using a 1.5-T MRI system (Signa HDx 1.5T; GE Healthcare, Milwaukee, WI, USA) with an 8-channel body array coil (GE Healthcare).

The volunteers were placed in the prone position with breath held after inspiration during examination.

Before real cine MRI, coronal images (FIESTA sequence: TR, 3.4 ms; TE, 1.1 ms; flip angle, 75°; slice thickness, 10 mm; matrix,  $256 \times 256$ ; field of view, 450 mm) of the entire abdomen were obtained, and the best slice reflecting the maximum length of the small bowel was determined.

A successive coronal scan consisting of 70 images in 35 s was obtained thrice in the respective selected plane. A steady-state free precession sequence (FIESTA sequence: TR, 3.4 ms; TE, 1.1 ms; flip angle, 75°; slice thickness, 10 mm; matrix, 256  $\times$  256; field of view, 450 mm) was used for imaging.

Imaging was performed in three series at 0, 10, 20, 30, 40, and 50 min after drinking tap water.



# Imaging analysis

Step 5.

Image evaluations were performed by consensus between two radiologists with 9 and 32 years of experience reading gastrointestinal images, who were blinded to information about the administered substances (TJ-100 or lactose).

A single loop in the left upper abdomen that stayed in a slice section during each scanning period and represented the patterns of contraction of other loops in the left upper abdomen was selected as a representative loop for the jejunum. In the same way, another loop in the right lower abdomen was selected as a representative loop for the ileum.

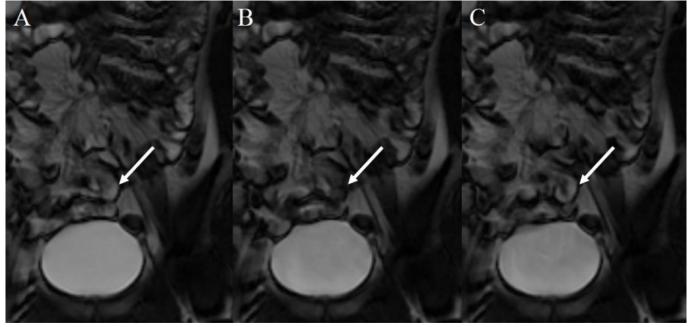
Cine MRI images were analyzed for the frequency of bowel contraction (contraction frequency) of the representative loops in the jejunum and ileum in respective phases. The frequencies of contraction in the representative bowel loops were counted visually on cine MRI.

The results for the contraction frequency and distention score from three scans were added together in the respective phase.

# Evaluation of bowel contraction

# Step 6.

Distended bowel loops were filled with fluid and demonstrated high intensity on MRI with our sequence, while collapsed bowel loops demonstrated low intensity that represented the intensity of the bowel wall, and the cycle of bowel contraction (dilation, collapse, and re-dilation) was reflected on cine MRI. Bowel contraction was judged as "full contraction = 1" when the entire cycle of contraction was confirmed, and it was judged as "half contraction = 0.5" when the dilated intestine collapsed or the collapsed intestine dilated (A-C).

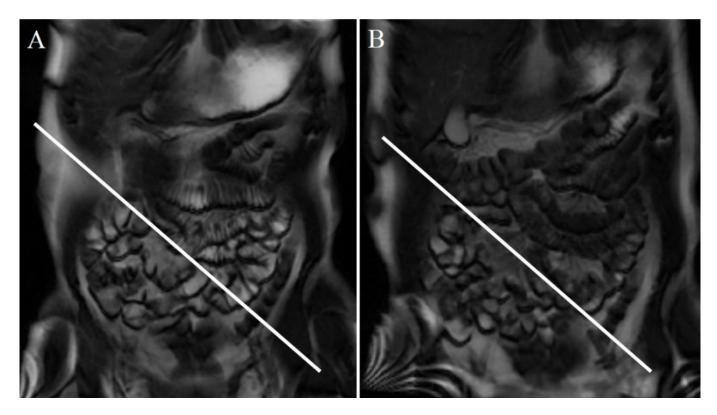


## Evaluation of bowel distention

## Step 7.

The degree of jejunal and ileal distention (distention score) was then assessed visually and scored using a 3-grade ranking. The distention score was judged as "0" when less than 30% of the loops of the jejunum or ileum were dilated, with fluid demonstrating high intensity on MRI. Similarly, the distention score was judged as "1" when between 30% and 70% of the loops of the jejunum or ileum were dilated and as "2" when more than 70% of the loops were dilated, with fluid demonstrating high intensity on MRI.

The example images are shown as below. Both the jejunum and ileum are well filled with fluid (>70%), and their bowel distention scores are "2" (A). The jejunum is filled with a small amount of fluid (<30%), and its bowel distention score is "0" (B). The ileum is filled with a moderate amount of fluid (30%-70%), and its bowel distention score is "1."



## Statistical analysis

## Step 8.

The mean contraction frequency and distention score in the respective phase was calculated by averaging the data of all volunteers. The Wilcoxon signed-rank test was used to compare the mean contraction frequency and distention score in the respective phase between the TJ-100 and lactose groups. The correlation between the added bowel contraction frequency and bowel distention score was evaluated using Spearman's rank correlation coefficient. Statistical tests were performed using SPSS statistics 22 (IBM Corp., Armonk, NY, USA). A *P*-value <0.05 was considered to indicate a statistically significant difference.