

**21. Others****References**

Fujinami H. Assessment of diminished peristalsis using Shakuyakukanzoto (TJ-68) as premedication for endoscopic retrograde cholangiopancreatography (ERCP): randomized placebo-controlled trial. *Nikkei Medical (Supplement)* 2010; 8: 34 (in Japanese).

**Fujinami H, Kudo T, Nakayama Y, et al. Assessment of diminished peristalsis using Shakuyakukanzoto (TJ-68) as premedication for endoscopic retrograde cholangiopancreatography (ERCP): a randomized, placebo-controlled trial. *Gastrointestinal Endoscopy* 2010; 71: AB227.**

**1. Objectives**

To evaluate the effectiveness of shakuyakukanzoto (芍薬甘草湯) as premedication for ERCP in suppressing duodenal peristalsis.

**2. Design**

Randomized controlled trial (RCT).

**3. Setting**

No. 3 Department of Internal Medicine, Toyama University Hospital, Japan.

**4. Participants**

Thirty patients undergoing ERCP (20 males, 10 females; mean age 66.5 years).

**5. Intervention**

Arm 1: shakuyakukanzoto group: TSUMURA Shakuyakukanzoto (芍薬甘草湯) Extract Granules 5.0 g dissolved in 50 mL warm water (n=10).

Arm 2: anticholinergic group: scopolamine butylbromide solution 20 mg/mL intravenous injection (n=10).

Arm 3: placebo group: warm (37°C) water 50 mL (n=10).

The liquids in arm 1 and arm 3 were sprayed directly into the duodenum through an endoscope.

**6. Main outcome measures**

Assessment by DVD image analysis of the time required to stop peristalsis (RT: seconds) and period of cessation of peristalsis (DT: minutes).

**7. Main results**

Peristalsis stopped in 8/10 patients in arm 1, 10/10 in arm 2, and 0/10 in arm 3. RT was  $76.0 \pm 23.9$  in arm 1 and  $42.4 \pm 6.1$  in arm 2. DT was  $11.3 \pm 4.2$  in arm 1 and  $14.9 \pm 5.3$  in arm 2. There was no significant difference in RT and DT between these groups.

**8. Conclusions**

Shakuyakukanzoto is effective as premedication for ERCP in suppressing duodenal peristalsis. Its effects are similar to scopolamine butylbromide solution 20 mg/mL intravenous injection.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

Not mentioned.

**11. Abstractor's comments**

In clinical terms, this is a highly significant clinical trial because it assessed peristalsis in three groups during actual ERCP. Anticholinergics are generally used to reduce peristaltic action for upper gastrointestinal endoscopy and ERCP, but they are contraindicated for patients with ischemic heart disease, prostatic hypertrophy, glaucoma, etc. Such patients cannot take anticholinergics. Shakuyakukanzoto appears to be a very safe premedication that will reliably suppress peristalsis in such patients.

**12. Abstractor and date**

Kogure T, 31 December 2012.