21. Others

References

Fujinami H, Kajiura S, Nishikawa J, et al. The influence of duodenally-delivered Shakuyakukanzoto (Shao Yao Gan Cao Tang) on duodenal peristalsis during endoscopic retrograde cholangiopancreatography: a randomised controlled trial. *Chinese Medicine* 2017; 12: 3: 1-6. doi: 10.1186/s13020-016-0125-6. Pubmed ID: 28077962

1. Objectives

To evaluate the inhibitory effect of intraduodenal administration of shakuyakukanzoto（芍薬甘草湯）on duodenal peristalsis during endoscopic retrograde cholangiopancreatography (ERCP)

2. Design

Randomized controlled trial (RCT)

3. Setting

One university hospital (department of internal medicine), Japan

4. Participants

Twenty-eight patients undergoing ERCP

5. Intervention

Arm 1: TSUMURA Shakuyakukanzoto（芍薬甘草湯）Extract Granules 5.0 g dissolved in 50 mL of warm water (concentration, 100 mg/mL), endoscopically sprayed once towards the major papilla of the duodenum (n=15)

Arm 2: Warm water as placebo sprayed in a similar manner (n=13)

6. Main outcome measures

Duodenal peristalsis was assessed using a 4-grade scoring system: +0 = no peristalsis and easy cannulation; +1 = slight peristalsis and easy cannulation; +2 = moderate peristalsis and difficult cannulation; +3 = severe peristalsis and impossible cannulation.

Primary endpoint: Duodenal peristalsis inhibition rate (i.e., proportion of patients with inhibition of grade +0 or +1 peristalsis).

Secondary endpoints: Required time (RT [seconds]) from dosing to inhibition of peristalsis, and stop duration time (DT [minutes]) of peristalsis

7. Main results

The analysis was conducted on 10 patients in Arm 1 and 9 patients in Arm 2, after exclusion of 5 patients in Arm 1 and 4 patients in Arm 2 who had no evident duodenal peristalsis at duodenoscopy. In Arm 1, duodenal peristalsis was inhibited in 8 (80%) of the 10 patients, and the RT was 76.0 ± 23.9 seconds and the DT was 11.3 ± 23.9 minutes. In Arm 2, inhibition of duodenal peristalsis occurred in no patients (0%), with RT and DT not measurable.

8. Conclusion

Endoscopic spraying of shakuyakukanzoto as premedication for ERCP inhibits duodenal peristalsis and allows easy cannulation.

9. From Kampo medicine perspective

None

10. Safety assessment in the article

Serum potassium was measured for detection of pseudoaldosteronism, but showed no significant difference between the two groups. No safety issues were noted.

11. Abstractor's comments

This is the first report of an RCT demonstrating that endoscopically sprayed shakuyakukanzoto solution in ERCP can inhibit duodenal peristalsis and permits easy cannulation. Typically, premedication before ERCP uses intravenous anticholinergic agents or glucagon, but adverse reactions to these agents can be problematic especially in elderly patients. If endoscopically sprayed shakuyakukanzoto is effective, the approach is of great significance. The reported mean time to the onset of action was 1+ minutes and mean duration of action was 11 minutes, which seem quite acceptable in clinical practice. However, since the sample size was small in this study, confirmation in a larger sample is warranted. In addition, since the warm water described as the placebo must be obviously different in appearance from shakuyakukanzoto solution, in a strict sense the warm water should probably be described as the "control" rather than the "placebo". It may also worth conducting an RCT using an intravenous anticholinergic agent as a control.

12. Abstractor and date

Motoo Y, 1 June 2020.