11. Gastrointestinal, Hepato-Biliary-Pancreatic Diseases

Reference

Seki M, Fujioka M, Hatano T, et al. Differences between the effects of sho-saiko-to, gorei-san, and toki-shakuyaku-san on the sphincter of Oddi - An intraoperative cholangiomanometric study -. *Nihon Toyo Igaku Zasshi* (*Japanese Journal of Oriental Medicine*) 1993; 43: 395-402 (in Japanese with English abstract).

1. Objectives

To evaluate the effects of shosaikoto (小柴胡湯), goreisan (五苓散), and tokishakuyakusan (当帰芍薬散) on the sphincter of Oddi.

2. Design

Randomized controlled trial (RCT).

3. Setting

One university hospital, Japan.

4. Participants

Forty-nine patients who were admitted for gallstone disease and underwent cholecystectomy.

5. Intervention

Arm 1: treatment with TSUMURA Shosaikoto (小柴胡湯) Extract Granules 2.5 gt.i.d. for 6.6±4.2 days before surgery (n=8).
Arm 2: treatment with TSUMURA Goreisan (五苓散) Extract Granules 2.5 gt.i.d. for 7.8±6.0 days before surgery (n=12).
Arm 3: treatment with TSUMURA Tokishakuyakusan (当帰芍薬散) Extract Granules 2.5 gt.i.d. for 8.2±6.3 days before surgery (n=5).
Arm 4: bed rest only (n=24).

6. Main outcome measures

Biliary pressure (basal pressure, BP; perfusion pressure, PP; the time for biliary pressure to normalize, T)

7. Main results

At a perfusion rate of 0.1 mL/s, there were no among-arm differences in BP and PP. Regarding the biliary pressure curve, only shosaikoto resulted in significantly decreased $T_{1/2}$, $T_{1/4}$, and $T_{1/5}$ compared with the control (P<0.02–0.05). At a perfusion rate of 0.5 mL/s, PP was significantly higher in arms 1 and 2 than in arm 4. Regarding the biliary pressure curve, only shosaikoto resulted in significantly decreased $T_{1/4}$ and $T_{1/5}$ compared with the control (P<0.01).

8. Conclusions

Shosaikoto and goreisan both lower the threshold of biliary pressure, and shosaikoto results in a rapid relaxation of the sphincter of Oddi.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

This clinical trial evaluated biliary pressure as an endpoint in 4 groups. It provides valuable insights. The authors speculate that the treatment may prevent bile stasis.

12. Abstractor and date

Kogure T, 8 August 2008, 1 June 2010, 31 December 2013.