

**11. Gastrointestinal, Hepato-Biliary-Pancreatic Diseases****Reference**

Takagi S. Increase of urinary 6-keto-prostaglandin F1 $\alpha$  level by preoperative administration of gorei-san or toki-shakuyaku-san to the patients of gallbladder stones or polyps. *Wakan Iyaku Gakkaishi (Journal of Medical and Pharmaceutical Society for WAKAN-YAKU)* 1992; 9: 32-9 (in Japanese with English abstract).

**1. Objectives**

To evaluate the effects of goreisan (五苓散) and tokishakuyakusan (当归芍薬散) on urinary 6-keto-prostaglandin F1 $\alpha$  excretion in patients with gallbladder stones or polyps.

**2. Design**

Randomized controlled trial (RCT).

**3. Setting**

One university hospital, Japan.

**4. Participants**

Twenty-nine female patients who underwent cholecystectomy for gallbladder stones or polyps.

**5. Intervention**

Arm 1: TSUMURA Goreisan (五苓散) Extract Granules (n=6).

Arm 2: TSUMURA Tokishakuyakusan (当归芍薬散) Extract Granules (n=6).

Arm 3: TSUMURA Shosaikoto (小柴胡湯) Extract Granules (n=6).

Each preparation was administered at 2.5 g t.i.d. before meals for 5 or 6 days before surgery.

Arm 4: no continuous drug therapy (n=11).

**6. Main outcome measures**

Urinary excretions of prostaglandin E1 (PGE1) and 6-keto-prostaglandin F1 $\alpha$  (6-keto-PGF1 $\alpha$ ).

**7. Main results**

There was no significant difference in urinary PGE1 excretion throughout the treatment course between each arm of treatment and the control arm (arm 4). Urinary 6-keto-PGF1 $\alpha$  excretion was increased significantly on postoperative days 1 and 5–7 in arm 1 ( $P<0.05$ ) and on postoperative days 1 and 3–7 in arm 2 ( $P<0.02$ – $0.001$ ). The urinary 6-keto-PGF1 $\alpha$  excretions were not significantly different between arm 3 and arm 4, as well as between arm 1 and arm 2.

**8. Conclusions**

Preoperative administration of goreisan or tokishakuyakusan before cholecystectomy results in increased postoperative urinary excretion of 6-keto-PGF1 $\alpha$ .

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

Not mentioned.

**11. Abstractor's comments**

The author of the study deserves praise for conducting a 4-group RCT. The determination of relationship between urinary excretion and clinical outcome would make the study more clinically meaningful.

**12. Abstractor and date**

Kogure T, 8 August 2008, 1 June 2010, 12 October 2011, 31 December 2013.