

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

Nishizawa Y, Nishizawa Y, Goto HG, et al. Prospective multicenter randomized group-parallelled study: effect of Chinese traditional herb medicine, jiu-wei-bing-lang-tang (Japanese name: kumi-binro-to) on constipation in elderly patients with renal dialysis. *Kampo Kenkyu (Kampo Research)* 2004; 388: 132-8 (in Japanese). Ichushi Web ID: 2004202082

**1. Objectives**

To evaluate the efficacy and safety of kumibinroto (九味檳榔湯) for chronic constipation in elderly dialysis patients.

**2. Design**

Randomized controlled trial (RCT).

**3. Setting**

Clinics and other services, Osaka, Japan.

**4. Participants**

Three-hundred and eighteen patients who were 75 years or older and on dialysis were enrolled during 15 years.

**5. Intervention**

Arm 1: treatment with Kotaro Kumibinroto (九味檳榔湯) Extract Fine Granules 2g, t.i.d., n=160.

Arm 2: treatment with magnesium laxative 2.0 g/day in three divided doses, n=158.

Duration of the study was 9 months.

**6. Main outcome measures**

Number of urges to have bowel movements and dosage of the laxatives (Western medicines) combined with the study drug.

**7. Main results**

Both the number of urges to have bowel movements and the dosage of the combined laxatives were significantly more improved in arm 1 than in arm 2. Symptoms associated with bowel movements were also significantly improved.

**8. Conclusions**

Kumibinroto is more effective than magnesium laxative for improving the number of bowel movements and the dosage of the combined laxatives in elderly dialysis patients with chronic constipation.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

Fewer adverse effects were reported in arm 1 than in arm 2 (data not shown). There were no abnormal examination findings.

**11. Abstractor's comments**

Although the word "multicenter" was mentioned in this article, none of the actual clinics, in contradistinction to research laboratories where this clinical trial was conducted, was specified. The authors conducted a 9-month, prospective, randomized study in 318 patients over a long period (15 years). Unfortunately, neither the number of withdrawals from the study nor the number of subjects included in the analysis was reported. Kumibinroto does not have a potent laxative effect. This study suggested that kumibinroto, combined with western laxatives, is more effective and safer than magnesium laxative for chronic constipation in elderly dialysis patients. Magnesium laxative, however, needs to be carefully administered and may cause hypermagnesemia in patients with renal impairment. Therefore, this type of laxative is usually avoided in patients undergoing hemodialysis. Regarding this point, the types and dosage of the western laxatives combined with the study drug are to be reported.

**12. Abstractor and date**

Okabe T, 15 June 2007, 1 April 2008, 1 June 2010.