Task Force for Evidence Reports / Clinical Practice Guideline Committee for EBM, the Japan Society for Oriental Medicine

# 15. Ante/Post-partum Diseases

# References

Sakuma K, Ushiroyama T, Akise D, et al. Clinical efficacy of kyukichoketsuin for regulation of puerperal psychosomatic functions. *Sanfujinka no Shinpo (Advances in Obstetrics and Gynecology)* 2002; 54: 80-6 (in Japanese with English abstract). Ichushi Web ID: 2002151144 MOL, MOL-Lib Ushiroyama T, Sakuma K, Souen H, et al. Therapeutic effects of kyuki-choketsu-in in restoring postpartum physical condition. *The American Journal of Chinese Medicine* 2003; 31: 437-44. CENTRAL ID: CN-00457564, Pubmed ID: 12943174

## 1. Objectives

To evaluate the efficacy and safety of kyukichoketsuin (キュウ帰調血飲) for puerperal psychosomatic disorder.

## 2. Design

Randomized controlled trial using sealed envelopes for allocation (RCT-envelope).

## 3. Setting

Osaka Medical College Hospital and associated facilities, Japan.

## 4. Participants

One-hundred and seventy-one women who had a normal delivery.

### 5. Intervention

Arm 1: daily administration of 6.0 g/day of Kanebo Kyukichoketsuin (キュウ帰調血飲) Extract Fine Granules for up to 1 month from the day of delivery (n=85).

Arm 2: administration of 0.375 mg/day of ergometrine (n=86).

# 6. Main outcome measures

Length of uterine fundus, blood hemoglobin concentration, body temperature, and amount of lactation measured 1 to 6 days postpartum.

Lochia, lactation, and mental state evaluated by questionnaire.

# 7. Main results

In arm 1, uterine contraction on postpartum day 5 was significantly greater, blood hemoglobin concentration was significantly higher, and mean amount of lactation was significantly increased from postpartum day 4 onward. The number of patients with subjectively rated depression in arm 1 was approx. half that in arm 2.

# 8. Conclusions

Kyukichoketsuin is more effective than ergometrine for some patients with puerperal psychosomatic symptomatology.

### 9. From Kampo medicine perspective

The crude-drug components of kyukichoketsuin associated with oxytocic, lactogenic, or psychotropic activity are mentioned in the discussion.

### 10. Safety assessment in the article

No adverse drug reactions occurred in either arm.

### **11.** Abstractor's comments

In Japan, randomization by the RCT-envelope method tends not to be maintained. This study suggests the partial efficacy of kyukichoketsuin for some patients with puerperal psychosomatic symptoms. Kyukichoketsuin is also known by a name of kyukihoketsuto and considered to be effective for various postpartum symptoms including *qiketsukyoson* (気血虚損, qi and blood deficiencies), *hiikyojaku* (脾胃虚弱, hypofunctioning of the spleen and stomach), *orofugyo* (悪露不行, lochiometra), *kyoketsukata* (去血過多, hypermenorrhea), *inshokusissetsu* (飲食失節, crapula), and *dokisosho* (怒気相衝, anger) (In: *Wanbinghuichun* [萬病回春]: *Recovery from All Ailments*).

### **12.** Abstractor and date

Okabe T, 15 June 2007, 1 April 2008, 1 June 2010, 31 December 2013.