

14. Genitourinary Tract Disorders (including Climacteric Disorders)**Reference**

Hiramatsu M, Maehara I, Takahashi M, et al. Treatment experience with saikokaryukotsuboreito and hochuekkito in male infertility patients*. *Kampo Igaku (Kampo Medicine)* 1993;17: 246–8 (in Japanese).

1. Objectives

To objectively evaluate the positive effect of saikokaryukotsuboreito (柴胡加竜骨牡蠣湯) or hochuekkito (補中益氣湯) monotherapy on sperm profiles of male infertility patients.

2. Design

Randomized controlled trial (RCT).

3. Setting

Four facilities including the Department of Urology, Tohoku University Hospital, Japan.

4. Participants

Twenty-eight patients diagnosed with oligozoospermia (sperm concentration of $<20 \times 10^6/\text{mL}$) or asthenospermia (motility of $<50\%$) at the above facilities between February 1990 and March 1992.

5. Intervention

Arm 1: TSUMURA Saikokaryukotsuboreito (柴胡加竜骨牡蠣湯) Extract Granules 2.5 g t.i.d., before meals for 12 weeks (n=12).

Arm 2: TSUMURA Hochuekkito (補中益氣湯) Extract Granules 2.5 g t.i.d., before meals for 12 weeks (n=16).

6. Main outcome measures

Sperm parameters including sperm concentration, motility, and sperm motile efficiency index (SMEI); and luteinizing hormone (LH), follicle stimulating hormone (FSH), testosterone, and prolactin levels. Global improvement evaluated at baseline and at weeks 4, 8, and 12 of treatment.

7. Main results

Both saikokaryukotsuboreito and hochuekkito significantly increased sperm motility and SMEI at 8 weeks of treatment but had no effect on sperm concentration or hormone levels. However, SMEI returned to baseline level at 12 weeks of treatment with hochuekkito. Saikokaryukotsuboreito and hochuekkito markedly improved sperm concentration (in 41.7% and 18.8% of patients, respectively) and sperm motility (in 41.7% and 50.0% of patients, respectively). Furthermore, 75.0% and 37.5% of patients showed moderate or marked global improvement, respectively.

8. Conclusions

Saikokaryukotsuboreito or hochuekkito monotherapy improves sperm parameters and is effective for male infertility.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

While an effective therapy for male infertility has not yet been established, this study demonstrated the effectiveness (overall efficacy and improved sperm parameters) of Kampo medicines in clinical practice. Particularly, saikokaryukotsuboreito increased sperm concentration to $20 \times 10^6/\text{mL}$ or higher and sperm motility $\geq 30\%$ in more than 40% of patients, increasing the number of candidates for artificial insemination and expectations for spontaneous pregnancy in clinical practice. However, since therapy was not prescribed according to *sho* (証, pattern) and random assignment to an experimental or control drug was not performed, the results of this study do not necessarily reflect true drug efficacy. The mechanism of action of Kampo medicines was not considered, and therefore in a future study protocol, the drug should be prescribed on the basis of *sho* (証, pattern) (*jitsu* [実, excess] or *kyo* [虚, deficiency]), *saiko-sho* (柴胡証), and presence or absence of *jinkyō* (腎虚, kidney deficiency).

12. Abstractor and date

Ushiroyama T, 20 August 2008, 1 June 2010.