14. Genitourinary Tract Disorders (including Climacteric Disorders)

Reference

Kazama T. Male infertility*. *Current Therapy* 1988; 6: 1683–6 (in Japanese).

1. Objectives

To evaluate the efficacy and safety of hochuekkito (補中益気湯) in the treatment of male infertility in comparison with Kallikrein (kallidinogenase).

2. Design

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

3. Setting

Department of Urology, Toyama Medical and Pharmaceutical University Hospital, Japan.

4. Participants

Forty-two patients (including ten withdrawals) diagnosed with male infertility (sperm count, 10–40 × 10^6/mL) at the above facility between January 1987 and January 1988.

5. Intervention

Arm 1: hochuekkito (補中益気湯) (manufacturer, not specified) 2.5 g t.i.d., before meals (n=16).
Arm 2: Carnaculin Capsule (kallinogenase 150 IU) t.i.d., after meals (n=16).
Treatment duration: 12 weeks (up to 36 weeks).

6. Main outcome measures

Sperm profiles including sperm concentration, motile sperm count, and percentage of motile sperm evaluated at baseline and week 12 of treatment. Treatment was considered effective if sperm concentration increased by $\geq 20 \times 10^6$/mL and motility increased ≥ 20%.

7. Main results

Sperm concentration increased in 56.3% of the patients in arm 1 and 25.0% of the patients in arm 2, and motility increased in 25.0% of the patients in arm 1 and 18.8% of the patients in arm 2. In addition, the total count of motile sperm was higher in the hochuekkito group than in the kallidinogenase group, although the between-group difference was not significant.

8. Conclusions

Treatment with hochuekkito confers a favorable outcome without adverse reactions and is therefore useful and indicated for male infertility.

9. From Kampo medicine perspective

Although drug prescription was not based on *sho* (証, pattern) in this study, activities including peripheral vasodilation, lipid metabolism improvement, protein synthesis promotion, and immunostimulation are suggested.

10. Safety assessment in the article

No adverse reactions occurred in both arms.

11. Abstractor's comments

No therapeutic approach to male infertility is currently established. This controlled study comparing hochuekkito with kallidinogenase (a conventional western medicine with reported efficacy for treatment of male infertility) demonstrated that hochuekkito confers a favorable clinical outcome with no adverse reactions. This study suggests that hochuekkito is a viable pharmacotherapeutic option for treating male infertility. However, sperm motility was not necessarily improved in all patients of this study but varied between individuals, indicating the importance of *sho*. Additionally, probably because the study period (12 weeks) was too short, successful pregnancy, a general endpoint of fertility treatment, was not reported, making it impossible to know whether sperm quality was improved enough to ensure pregnancy. It would be interesting to find out the diagnosis (based on the concept of oriental medicine *sho*) of patients responding favorably to hochuekkito and the characteristics of those responding poorly to it. Future studies using a protocol focusing on *sho* are expected to investigate the relationship between improved sperm profile and pregnancy rate in hochuekkito-treated patients, as well as ascertain the true therapeutic effect of hochuekkito on male infertility.

12. Abstractor and date

Ushiroyama T, 20 August 2008, 1 June 2010.