14. Genitourinary Tract Disorders (including Climacteric Disorders)

Reference

Horiba M, Kato S, Tanaka T, et al. Clinical validity of gosha-jinki-gan in the treatment of chronic prostatitis - open comparative study with gosha-jinki-gan vs ciprofloxacin -. *Gendai Toyo Igaku* (*The Journal of Traditional Sino-Japanese Medicine*) 1994; 15: 37–44 (in Japanese).

1. Objectives

To evaluate the efficacy and safety of goshajinkigan (牛車腎気丸) in the treatment of chronic prostatitis.

2. Design

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

3. Setting

One hospital, Japan.

4. Participants

Fifty-eight patients with chronic prostatitis.

5. Intervention

Arm 1: TSUMURA Goshajinkigan (牛車腎気丸) Extract Granules 2.5 g t.i.d. for 4 weeks (n=15).
Arm 2: ciprofloxacin 200 mg b.i.d. for 4 weeks (n=15).
Arm 3: TSUMURA Goshajinkigan (牛車腎気丸) Extract Granules 2.5 g t.i.d. + ciprofloxacin 200 mg b.i.d. for 4 weeks (n=14).
Arm 4: serratiopeptidase 10 mg t.i.d. for 4 weeks (n=14).

6. Main outcome measures

Subjective symptoms, prostate palpation findings, and white blood cell (WBC) in expressed prostatic secretion.

7. Main results

The analysis population consisted of a total of 48 patients: 14, 13, 9, and 12 patients in arm 1, arm 2, arm 3, and arm 4, respectively. Subjective symptoms were improved in 60.0%, 54.5%, 68.1%, and 33.3% of patients in arms 1 to 4, respectively, at 2 weeks; and in 80.0%, 66.7%, and 71.4% of patients in arms 1 to 3, respectively, at 4 weeks. Prostate palpation findings were improved in 21.5%, 10.0%, 14.3%, and 20.0% of patients in arms 1 to 4, respectively, at 2 weeks; and in 28.6%, 11.1%, and 44% of patients in arms 1 to 3, respectively, at 4 weeks. Normalization of WBC count in expressed prostatic secretion was noted in 12.5%, 11.1%, 28.6%, and 12.5% of patients in arms 1 to 4, respectively, at 2 weeks; and 30%, 12.5%, and 16.7% in arms 1 to 3, respectively, at 4 weeks. The efficacy rate judged by investigators was 85.7%, 63.6%, 88.8%, and 25% in arms 1 to 4, respectively, showing significantly higher efficacy in arm 1 than in arm 4 ($P<0.05$). As well, higher efficacy was obtained in arm 3 than in arm 4 ($P<0.05$).

8. Conclusions

It was suggested that Goshajinkigan is effective for chronic prostatitis.

9. From Kampo medicine perspective

Mentioned in the discussion section of the reference.

10. Safety assessment in the article

Mild adverse drug reactions were observed in 6 and 1 patient receiving ciprofloxacin and goshajinkigan, respectively, for a total of 7. The reactions were gastrointestinal symptoms, central nervous system symptoms, and allergic symptoms occurring in 3, 3, and 1 patient, respectively. The adverse reaction to goshajinkigan was intraoral inflammation in 1 patient.

11. Abstractor's comments

Although using seal envelopes for allocation is likely to have compromised randomization, this clinical trial demonstrated the efficacy of goshajinkigan for chronic prostatitis. A future randomized controlled trial is expected to be performed and to use an improved method of randomized allocation, statistical analysis of results, more objective variables, and larger sample size.

12. Abstractor and date

Okabe T, 28 August 2008, 1 June 2010, 31 December 2013.