Evidence Reports of Kampo Treatment

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

5. Psychiatric/Behavioral Disorders

Reference

Sato Y, Horita H, Adachi N, et al. Effect of oral administration of prostaglandin E1 on erectile dysfunction. *British Journal of Urology* 1997; 80: 772-5.

1. Objectives

To compare the efficacy and safety of limaprost, an oral prostaglandin E1 derivative, with those of goshajinkigan (牛車腎気丸) in the treatment of erectile dysfunction.

2. Design

Quasi-randomized controlled trial (quasi-RCT).

3. Setting

Not mentioned (the authors belong to Department of Urology, Sapporo Medical University and Sanjukai Hospital), Japan.

4. Participants

Fifty patients with mild erectile dysfunction.

5. Intervention

Arm 1: treatment with goshajinkigan (牛車腎気丸; manufacturer, not specified) 2.5 g t.i.d. for 8 weeks (n=25; of these 24 were included for analysis).

Arm 2: treatment with limaprost 10 µg t.i.d. for 8 weeks (n=25; of these 24 were included for analysis).

6. Main outcome measures

Achievement of two consecutive vaginal penetrations, nocturnal penile tumescence measurements, and self-reported penile rigidity (0-5 points) and maintenance of erection (0-5 points).

7. Main results

Four of 24 analyzable patients in arm 1 and 11 of 24 in arm 2 achieved at least two consecutive vaginal penetrations; the rate of response was significantly higher in arm 2 than in arm 1 (P<0.05). However, not all patients who achieved vaginal penetrations experienced full erection. The mean increase of penile circumference was 6.0 ± 6.6 mm for 23 patients who had measurements in arm 2 and only 2.3 ± 5.8 mm for 21 patients in arm 1. The increase of penile circumference was significantly greater in arm 2 than in arm 1. There were no significant between-arm differences in the penile rigidity and maintenance of erection.

8. Conclusions

Limaprost, an oral prostaglandin E1 derivative, is more effective than goshajinkigan in the treatment of mild erectile dysfunction.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

One limaprost-treated patient developed facial flush.

11. Abstractor's comments

This study demonstrated that limaprost, an oral prostaglandin E1 analogue, was more effective than goshajinkigan in the treatment of mild erectile dysfunction. All patients in this study had achieved full erection after local injection of prostaglandin E. Limaprost resulted in a response in 45.1% of patients, but not in full erection. In this study, treatment assignment was in the order of patient presentation, but a randomized assignment is preferred.

12. Abstractor and date

Okabe T, 19 August 2008, 1 June 2010, 31 December 2013.