Evidence Reports of Kampo Treatment

Task Force for Evidence Reports, the Japan Society for Oriental Medicine
Note) The quality of this RCT has not been validated by the EBM committee of the Japan Society for Oriental Medicine.

14. Genitourinary Tract Disorders (including Climacteric Disorders)

Reference

Oh-oka H. Effect of Saireito for Prevention and Improvement of Urethral Stricture after Transurethral Resection of the Prostate. *Kampo Medicine* 2016; 67: 244-50 (in Japanese with English abstract). Ichushi Web ID: 2017003685, <u>J-STAGE</u>

1. Objectives

To evaluate the preventive effect of saireito (柴苓湯) on postoperative urethral stricture.

2. Design

Randomized controlled trial (RCT).

3. Setting

One hospital.

4. Participants

Prostatic hyperplasia patients (142) without overactive bladder, who underwent TUR-P between April 2011 and March 204; received lifestyle guidance at initial consultation, including instruction on fluid intake and sleep hygiene; and were administered an α -blocker as drug therapy. Times since diagnosis ranged from 3.5 to 5.5 (mean 4.3) years, and ages were 68 to 85 (mean 75.5) years.

5. Intervention

Arm 1: Saireito (柴苓湯) administration group (n=70)

Saireito (1g t.i.d before meals for 3 months) from first intake after TUR-P surgery

Arm 2: No administration group (n=72)

6. Main outcome measures

Primary outcome measures examined include preventive effect on urethral stricture after TUR-P surgery; the clinically verified effect of saireito on postoperative urethral stricture; and clinical utility when administering and when not administering saireito in patients who meet and who don't fit the "pattern" indicated for saireito, defined as depressed liver qi transforming into fire, spleen qi deficiency, and water retention.

7. Main results

- 1) Saireito administration significantly reduced the occurrence of postoperative urethral stricture (P=0.043).
- 2) Improvement was observed after saircito administration for urethral stricture in 5 out of 8 participants in the no administration group.
- 3) Comparison of the group without the non-saireito pattern and without medication, with the group with the saireito pattern and with medication showed significantly lower frequency of urethral stricture in the latter (P=0.042).

8. Conclusions

Saireito administration after TUR-P surgery prevents postoperative urethral stricture and its improvement of stricture in clinically ascertained postoperative urethral stricture is acknowledged. It is acknowledged as having most effectiveness for saireito pattern patients.

9. From Kampo medicine perspective

During and after TUR-P, patients are considered to exhibit a half-exterior half-interior pattern; the heat-clearing action of saiko with ogon and the anti-inflammatory action of ogon with bukuryo, also medical insults such as the water dampness caused by perfusate arising from endoscopic surgery, and the urethral ischemia, etc. attributable to resectoscope are considered factors causing postoperative urethral stricture; so saireito, which combines the properties of goreisan, which has a diuretic effect, with shosaikoto, promises effects for postoperative urethral stricture.

10. Safety assessment in the article

The compliance rate across all patients was 88-100% (mean 95%), and there was no dropout due to adverse effect.

11. Abstractor's comments

This is an interesting clinical study designed to clarify the effects of saireito on postoperative urethral stricture. There was 1 clinically verified case of postoperative urethral stricture in the saireito group, and 8 in the no administration group, and the number of confirmed postoperative strictures was significantly smaller in the postoperative saireito administration group, which suggests that saireito administration is a very useful therapy. Hopefully future research will accumulate additional cases and further yield results that take "patterns" into account, and the results from treatment period, etc.

12. Abstractor and date

Kato Y, 18 May 2020.