11. Gastrointestinal, Hepato-Biliary-Pancreatic Diseases

Reference

Umemoto M, Nin T, Miuchi S, et al. Treatment of human dry mouth using various medicines. *Jibiinkoka Rinsho* (*Practica otologica*) 2007; 100: 145-52 (in Japanese with English abstract). Ichushi Web ID: 2007135958

1. Objectives

To compare the efficacy of bakumondoto (麦門冬湯) versus cevimeline hydrochloride hydrate (Evoxac) or nizatidine (Acinon) for treating dry mouth.

2. Design

Randomized controlled trial (RCT).

3. Setting

Gustatory Outpatient Clinic, Department of Otolaryngology, Hyogo College of Medicine, Japan.

4. Participants

One hundred patients with dry mouth (13 males and 87 females; mean age, 69.0 years). Patients with a basal salivary secretion rate of 3 mL/10 min or lower and a chewing-gum-stimulated salivary secretion rate of 10 mL/10 min or lower were included in the study. Exclusion criteria were Sjögren syndrome, diabetes mellitus, use of oral antihistamine or antipsychotic, asthma, ischemic heart disease, epilepsy, prostatic hyperplasia, and glaucoma.

5. Intervention

Arm 1: treatment with bakumondoto (麦門冬湯) (manufacturer, not specified) 3.0 g t.i.d. for 90 days in 24 patients (4 males and 20 females; mean age, 67.4 years), as the bakumondoto (麦門冬湯) group.

Arm 2: treatment with cevimeline hydrochloride hydrate 30 mg t.i.d. for 90 days in 42 patients (3 males and 39 females; mean age, 72.0 years), as the cevimeline group.

Arm 3: treatment with nizatidine 150 mg b.i.d. for 90 days in 34 patients (6 males and 29 females; mean age, 66.0 years), as the nizatidine group.

6. Main outcome measures

The basal rate and chewing-gum-stimulated salivary secretion rate after 90 days of treatment. Subjective symptoms were assessed using a questionnaire on a 4-point scale (“improvement”, “mild improvement”, “no change”, or “worsening”).

7. Main results

The rate of basal salivary secretion increased from 1.0±0.2 mL/10 min to 1.3±0.2 mL/10 min after treatment with bakumondoto, from 1.1±0.1 mL/10 min to 1.6±0.2 mL/10 min after treatment with cevimeline, and from 1.1±0.2 mL/10 min to 2.4±0.3 mL/10 min after treatment with nizatidine. The rate increases in the cevimeline and nizatidine groups were significant ($P<0.001$). The change in the rate of chewing-gum-stimulated salivary secretion after treatment with cevimeline and nizatidine were similarly significant ($P<0.001$). Both the basal rate and chewing-gum-stimulated salivary secretion rate were significantly different between the bakumondoto- and the nizatidine-treated groups (both $P<0.01$) but not between the bakumondoto- and the cevimeline-treated groups. Treatment with cevimeline or nizatidine led to “improvement” in subjective symptoms in 50–57% of patients and “improvement” or “mild improvement” in 85.7% of cevimeline-treated patients and 74.2% of nizatidine-treated patients. In contrast, only 4% of bakumondoto-treated patients noted “improvement”.

8. Conclusions

Cevimeline hydrochloride hydrate and nizatidine but not bakumondoto significantly increase both basal and stimulated salivary secretions and relieve subjective symptoms in patients with dry mouth.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

No patients reported “worsening” of symptoms. No adverse drug reactions occurred.

11. Abstractor’s comments

This is a well-designed and well-conducted RCT. The authors speculate that saponins in ginseng, a component of bakumondoto, activate salivary cells by increasing cell membrane permeability. According to their discussion, increase in cell membrane permeability alone does not directly increase the amount of saliva. This was suggested by the fact that dry mouth in most subjects in this trial was due to age-related atrophy and impairment of salivary gland cells. Further studies are expected.

12. Abstractor and date

Tsuruoka K, 12 February 2009, 1 June 2010, 31 December 2013.