

原 著

### 漢方薬による慢性難治性疾患の鎮痛効果： 麦門冬湯とブロムヘキシンの二次性シェグレン症候群に 対する鎮痛効果，無作為比較検討試験

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要旨：二次性シェグレン症候群 (S-SJS) に対して漢方薬の麦門冬湯 (TJ-29) とブロムヘキシシン (B) の多施設，前向き無作為抽出比較検討した。即ち，唾液・涙液分泌機能，慢性疼痛 (CP)，健康関連 QOL (H-QOL)，医療経済面，内科的慢性難治性疾患に基づく身体的，精神的，社会的，医療経済的苦痛，即ち，慢性疼痛，H-QOL 改善に対する効果を両薬を用いて前向き無作為比較試験で検討した。informed consent 後，S-SJS 患者を computer で無作為に 2 群に振り分け，A 群 (TJ-29：力価 6g/日)，(B 群：B12mg/日) を 1 年間，1 日 3 回，食間投与した。唾液・涙液分泌量は Saxon test, Schirmer's test で各々測定した。四肢皮膚温度は皮膚貼布型インジケーター プロチェッカー，唾液・涙液分泌自他覚症状，関節痛，咳嗽，喀痰排出度は VAS (0～100) で表現した。慢性疼痛は我々の開発した T-DRS 法などで，また，各種 H-QOL 即ち，H-DRS を比較検討した。①両群背景因子は何ら有意差を認めず，A 群のみが B 群に比較し有意の，②唾液分泌量増加，③唾液分泌自他覚症状改善を認め，A 群でのみ④涙液分泌量，同自他覚症状，⑤皮膚温度，関節痛，咳嗽，喀痰排出量，レイノー症状は有意改善を認めた。⑥慢性疼痛，H-QOL は A 群で B 群に比較し有意に改善した。⑧副作用，臨床検査値異常は A 群が B 群に比較し有意に少なく，⑨全般的改善度は A 群が B 群に比較し有意に優れていた。以上の結果から，S-SJS 各種慢性疼痛改善に TJ-29 使用が B 群に比較し有意に有効である可能性が示唆された。

索引用語：二次性シェグレン症候群，慢性難治性内科疾患，慢性疼痛，麦門冬湯，塩酸ブロムヘキシシン

### PAIN AND KAMPO MEDICINE Vol.14 (2004)

#### The Multicenter Randomized Comparative Study of Kampo Herbal Medicine, Mai-Men-Dong-Tang (Japanese name Bakumondo-To) Compared with Bromhexine on Salivary Secretion in Secondary Sjogren's Syndrome

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**Abstract:** Patients (n=847) with secondary Sjogren's Syndrome (S-SJS) which were induced by disorders related to other various collagen diseases are associated with sicca syndrome (SS), which consists of dry mouth and dry eye (sicca syndrome: SS). These characteristic symptoms, resulting from the decreased secretion of saliva and tears, have been found to be quite intractable. We investigated long-term randomized comparative therapeutic effects of traditional Kampo herb medicine, Mai-Men-Dong-Tang (MMDT; Japanese name: Bakumondo-to); TJ-29 or Bromhexine (B) on increasing secretion of saliva and tear, and SS related objective and subjective symptoms. These patients were randomizedly divided into two groups. TJ-29 was orally administered to patients with S-SJS who had been proven to be SS (Group A: n=424; MMDT: 6g/day, 3 times daily), (Group B: n=423; B: 12mg/day, 3 times daily) for 6 mo. The basic characteristics were significantly showed no difference between not the two groups. The improved effects of TJ-29 on dry mouth and dry eye was evaluated with subjective and objective symptoms in the group A but not in the group B. Saxon test and induced significant improved from 0.97 ± 0.13 to 2.18 ± 0.40 (g/2 min) (P<0.001) (Group B: from 0.99 ± 0.19 to 1.35 ± 0.37 (g/2 min: P<0.05) sokima's test was significantly improvement from 1.9 ± 0.5 to 9.7 ± 1.5 (ml/5 min) (P<0.01) (Group B: from 2.1 ± 0.7 to 2.5 ± 1.4 (ml/ 5 min: NS). These disease related symptoms such as cough, difficult excretion of sputums, arthralgia, Raynaud's phenomenon and other several symptoms significantly improved in the group A, but not in the group B. The chronic intractable internal medicals agony ie chronic pain evaluated on various scale such as total disease related symptoms (T-DRS) and its components, face scale and others were improved more in the group A than in the group B. Health related DRS ie H-QOL was significantly improved in the group A more than in the group B. Both adverse side effects and appearance of abnormal laboratory data during this trial were significantly less in the group A than in the group B.

The final global improvement rating 6 mo of TJ-29 therapy revealed that 69.6% (295 out of 424) of the patients were improved in their conditions in this trial (Group B: 4.2% 18 out 423, P<0.01). Tj-29 may be a useful medicine for SS in patients with S-SJS.

**Key words:** Bakumondo-to, Bromhexine hydrochloride

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