

## 原 著

## 漢方薬の内科疾患急性疼痛改善効果：麦門冬湯と塩酸ホミノベンとの高齢者急性気道炎疾患起因咳嗽に対する前向き多施設無作為比較検討試験

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**要旨：**内科疾患(IMD)においても急性疼痛(AP)は存在する。かぜ症候群後咳嗽に於いても咳嗽に基づく急性疼痛は少なくない。中枢的咳嗽抑制時に喀痰排出に困難化する。また、老人では唾液分泌能低下のため自覚他覚症状が多発する。今回、麦門冬湯(TJ-29)と塩酸ホミノベン(F)の咳嗽に基づく内科疾患のかぜ症候群後咳嗽に基づく急性疼痛に関する効果に関する前向き多施設無作為比較検討試験を施行した。インフォームドコンセント後、患者本人、家族2名以上の実筆署名をえた65歳以上老人でかぜ症候群後の激しい咳嗽疾患2096例を無作為に抽出、コンピューターで2群化、1群にTJ-29 9g/日 (1039例：A群)、他群にF160mg/日を (B群:n=1030例) 1日3回投与、自覚他覚症状、急性疼痛、Health related quality of life (H-QOL) 改善度、咳嗽、喀痰排出困難度、唾液分泌度をsaxon test、皮膚温度、関節痛をVASで求めた、急性疼痛程度は我々の開発したTotal disease related symptom (T-DRS法) 他で判定した。1) 両群背景因子に何ら有意差はなく、2) A群はB群に比較し咳嗽は有意に抑制し、同期間も短く、3) 喀痰排出はB群で抑制されなかったのに対しA群でのみ有意改善効果を示し、4) 皮膚温度、関節痛、口腔乾燥度などはA群でのみ改善された、5) AP改善程度はA群でB群に比較しT-DRS、その構成項目の有意改善を認めた(個人的DRSのみ変化なし)、6) 各種H-QOLはA群でB群に比較しより有意に改善を受けた。TJ-29は咳嗽を抑制するのみならず、muscarinic-receptorに作用し唾液分泌促進効果を有する。今回の結果はこれらTJ-29の総合的作用によると考えられ、漢方薬は一剤で多様な薬理効果を有し、医療経済上効率的である可能性も示唆された。

**索引用語：**麦門冬湯、かぜ症候群後咳嗽、塩酸ホミノベン、医療経済、急性疼痛

## PAIN AND KAMPO MEDICINE Vol.13 (2003)

**Beneficial Effect of Chinese Traditional Herbal Medicine, Mai-Men-Dong-Tang (Japanese Name:Bakumondo-to) on Acute Pain in Patients with Acute Internal Medical Disease: Antitussive Effect on Elderly Patients with Postinfectious Persistent Coughs, Prospective, Multicenter, Randomized Compative Trial between Mai-Men-Dong-Tang and Forminoben Hydrochloride**

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**Abstract:** A Chinese traditional herbal medicine, Mai-Men-Dong-Tang (MMDT, Japanese name:Bakumondo-to) TJ-29 has been used for the treatment of bronchitis and pharyngitis accompanied by severe coughs. In this trial, we examined whether or not TJ-29 had antitussive effects in elderly patients ( $\geq 65$  y) with postinfectious persistent coughs. Non-smoking elderly patients ( $\geq 65$  y) who met the following diagnostic criteria were selected as subjects: (1) those who had been coughing continuously for more than 3 weeks postinfectiously; (2) those who did not use angiotensin-converting enzyme inhibitors orally; (3) Those who had no history of nasal or paranasal disease and chronic pulmonary disease; (4) those who had normal chest rentenography, respiratory function, periper white blood cell count, normal periper eosinophil counts levels of C-reactive protein, and serum IgE concentrations. Subjects were randomized into two groups by computer: those given a dialy dose of 9g of TJ-29 extract granules orally for several weeks (group A:n=1039), and those given a daily dose of 160 mg forminoben hydroihloride (F) orally for several weeks (group B:n=1030). Using a cough diary, we compared and studied antitussive effects between the two groups. We also studied salivary secretion by Saxon test, tear secretion by Schimer's test, skin-temperature at extremities by skin patched thermostat checker, degree of arthralgia by the visual analogue scale (VAS), acute pain-score by our total-disease related symptoms (T-DRS), face scale, VAS, and several health related quality of life (H-QOL). There were no significant differences between the two groups in demographic characteristics. At the baseline, antitussive effects in group A were superior to those in group B ( $P<0.001$ ). Decrease of sputum-secretion also showed the same results ( $P<0.001$ ). Increase in secretion of both saliva and tear is only observed in group A. Increase in skin temperature at hands and limbs, and improvement of arthralgia was observed in group A. Ap scores were significantly improved in group A than in group B without identical-DRS. Group A was superior to group B ( $P<0.001$  vs baseline, group B). We obtained the same results in H-QOL ( $P<0.001$  vs group B without ADL FIM). Both appearance of abnormal laboratory data and adverse side effects were less observed in group A than in group B without Taiso-induced eosinophile pneumonias in group A ( $P<0.001$  vs groupB). The improved rate of antitussive effect in group A were higher than group B ( $P<0.001$ ). In the global improved ratio of all symptoms previously described, group A (over Improvement) was superior to group B ( $P<0.001$ ). In this prospective, multicenter randomized open comparative trial, we considered that MMTD was an effective treatment in non-smoking elderly patients with postinfectious persistent coughs, and it appears to demonstrate another elderly subject's specific subjective symptoms, internal medical disease-related acute pain and H-QOL. These results were considered in discussion.

**Key words:** Mai-Men-Dong-Tang, Postinfectious presistent cough, Fominoben hydrochloride, Medical economy acute pain

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