

原 著

牛車腎気丸と芍薬甘草湯の肝硬変患者の有痛性
こむら返りに対する鎮痛効果と安全性：
多施設無作為抽出，比較試験による効果の検討
— 牛車腎気丸の肝硬変症に伴う有痛性“こむら返り”に
対する臨床効果と安全 —

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要旨：多施設無作為抽出比較試験で肝硬変 (LC) 随伴有痛性こむら返り (PMC) をA群 (38例, M:F=31:7, 64.8±10.3歳), B群 (37例, M:F=31:6, 62.7±9.5歳) (背景因子有意差なし) にわけ各々牛車腎気丸 (GJG) : 90 mg/kg/day, 芍薬甘草湯投与 (SKT) : 50 mg/kg/day を12週間を投与した。LC随伴PMCによる各種慢性疼痛評価法 (ECP) (VAS-P, 総合QOL法他) とした。各種ECPはA群でB群に比較し有意早期改善され, 改善率もA群がB群より有意に高かった。副作用, 臨床検査値異常はA群がB群より有意に少なく, 有効以上症例はA群がB群より有意に多かった。以上より, 漢方治療上LC随伴PMC治療ではGJGがSKTより有意に秀れていることが示唆された。

索引用語：牛車腎気丸, 芍薬甘草湯, 有痛性こむら返り症, 肝硬変

PAIN AND KAMPO MEDICINE Vol.10 (2000)

A Randomized Paralleled Group Comparison in Multicenter Cooperation :
Analgesic Effect and Safety with Gosha-jinki-gan and Shakuyaku-kanzo-to
in the Treatment of Painful Muscle Cramps in Patients with Cirrhosis

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Abstract : In order to compare the relative safety and the analgesic effect of two Kampo medicines (TSUMURA Gosha-jinki-gan Extract Granules for Ethical Use (TJ-107 : GJG) and TSUMURA Shakuyaku-kanzo-to Extract Granules for Ethical Use (TJ-68 : SKT) on painful muscle cramps (PMC) in patients with liver cirrhosis (LC), we conducted 12 weeks of a controlled, paralleled comparison group test in multicenter cooperation on patients (75 cases) with PMC induced by LC. The patients were randomly assigned to one of the two treatment groups. [Group A. (oral administration of GJG : 90mg/kg/day : 38 cases (Male : Female=31 : 7, 64.8±10.3 years old, Group B : SKT (50mg/kg/day : 37 cases, Male : Female=31 : 6, 62.7±9.5 years old)] using a randomized table. There were no statistically significant differences among these two treatment groups in the clinical or laboratory data. The patients in group A had a significantly faster onset of responses and superior responses than group B by Total-QOL method and VAS-P, face rating scale and various QOL methods (MHAQ, OWB-score, and face scale). In the adverse drug-reaction and drug-induced abnormal laboratory data, Group B with SKT showed more significant differences than Group A. In Group A GJG showed more noted efficacy and safety than group B, because side effects were less apparent. In Group A and SKT induced abnormal laboratory data in Group B. Our results suggest that GJG is more effective than SKT for LC-induced PMC patients.

Key words : Gosha-jinki-gan, Sakuyaku-kanzo-to, efficacy, safety, painful muscle cramp, cirrhosis