ブシ末(調剤用)「ツムラ」を漢方処方薬に併用投与した症例における鎮痛効果・安全性及び用量の検討

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要旨: 従来品の修治ブシ末N(以下,TJ-3022)よりも鎮痛成分アコニチン型ジエステルアルカロイド(Mesaconitine,Jesaconitine)含量が約2.5倍であるブシ末(調剤用)「ツムラ」(以下,TJ-3023)が平成19年7月に薬価収載された。このTJ-3023と漢方処方薬を併用投与した症例における安全性と用量について検討した。対象はTJ-3022を処方していた39例(男性4例,女性35例)であるが3例は来院不可で脱落し,1例は薬疹出現により投与を中止したため35例である。平均年齢は68±13歳である。漢方処方薬は,当帰四逆加呉茱萸生姜湯,補陰湯,八味丸など22処方薬であり,その中,エキス製剤を用いた2例を除き他は全て煎液である。投与中のTJ-3022,2~4g/日をTJ-3023に切り替え,初期量0.7~1.5/日で開始して4週間投与し,その期間中におけるTJ-3023の鎮痛効果をVASと問診により評価した。VASは,TJ-3022投与中では43.4±11.9であったがTJ-3023投与後の4週目では20.0±10.5となり,問診では32例が軽くなったと,3例が不変と回答し,悪化例はなかった。またTJ-3023の投与量0.7~3.0/日は,TJ-3022の1/3~3/4に相当する。副作用をみとめたのは36例中2例であるがいずれも軽症であった.

索引用語:修治ブシ末N,ブシ末(調剤用)「ツムラ」,安全性, 鎮痛効果,ブシ末の副作用

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The Study of the Bushi-matsu (TSUMURA Processed Bushi Powder for Ethical Dispensing:TJ-3023) on the Safety and the Dosage in Patients Treated with Kampo Medicines

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Abstract: New type bushi-matsu (TSUMURA Processed Bushi Powder for Ethical Dispensing: TJ-3023) has 2.5 times of aconite type diester alkaloids (mesaconitine, jesaconotine etc.) as much as those in old type bushi-matsu (TSUMURA Shuchibushi Powder N for Ethical Dispensing: TJ-3022). The safety and the dosage of TJ-3023 were studied in patients treated with kampo medicines. TJ-3023, 0.7 ~ 3.0 g/kg were administered to 39 patients (4 males and 35 females: the average age was 68 ± 13) who had been treated with TJ-3022, 2.0 ~ 4.0 g/day, till then. Kampo medicine used in each patient was selected among 22 kinds (tokishigyakukagoshuyushokyoto, hoinnto, hachimigan etc.) was administered together. Kampo medicines were administered as decoctions with exception of 2 patients who were administered the extract granule. Analgesic effect was evaluated by the visual analogue scale (VAS) or the questioning. Three patients were omitted and 1 patient was stopped the medication by the occurrence of medicinal exanthema.

By the changing of TJ-3022 to TJ-3023, the VAS decreased to 20.0 ± 10.5 from 43.4 ± 11.9 . In questioning, the pain was improved in 32 patients, and the change for the worse was not recognized. The dosages of TJ-3023, $0.7 \sim 3$ g/day were equivalent to those of TJ-3022, $2.0 \sim 4.0$ g/day. Adverse effects were shown in 2 patients, but they were just slight.

Key words: TSUMURA Shuchibushi Powder N for Ethical Dispensing, TSUMURA Processed Bushi Powder for Ethical Dispensing, Safety, Analgesic effect, Adverse effect of bushi-matsu

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