中藥成藥中金屬濃度與人體暴露評估---以苗栗地區爲例

Metal Concentration and Human Exposure Assessment for Chinese Herbal Medicine''s Over-the-Counter Drugs---A Case Study of Maio-Li County

中文摘要

中藥在國人醫療行爲中佔有重要之地位，隨著中西醫學之合作，及一些實驗證明中藥在預防癌症，提升免疫力上確有功效，更使中藥在國際間的接受度日漸增加。惟時傳重金屬中毒案件，使部分人對其安全性產生疑慮，而裹足不前。是以本研究對苗栗縣民使用中藥者進行問卷調查，以調查其使用中藥之動機及意向，並抽樣市售中藥成藥四十八種，檢驗其含鉛、砷、鎘及汞之濃度，並探討其對人體健康是否會造成風險，進而供有關當局制定相關安全標準量用。檢驗結果，四十八種中藥成藥樣本中，砷之濃度均在新加坡政府規定藥物濃度之 5 ppm 以下。鉛之濃度均在中國植物藥現行標準之 10 ppm 以下。鎘之濃度部分，除蔘仲四物丸及八味地黃丸之濃度超過目前中國植物藥現行標準之 0.3 ppm 標準外，其餘四十六件成藥之濃度均在標準範圍內，三者均與其他研究相似。而汞之部分，共有十八件超出新加坡政府藥物規定之 0.5 ppm 標準。在風險評估方面，非致癌物質危險標的商數部分，長期服用時，以全樣本計算時，鉛、砷、鎘、汞之商數均未超過安全標準值 1，但以主治效能分別計算時，風溼關節疾病及明目功能之中藥成藥，鉛之商數超過安全標準值 1，而補血類及婦科疾病類之中藥成藥，汞之商數超過安全標準值 1。而在致癌物質危害標的商數部分，就目前有致癌強度標準值之砷進行評估，其結果長期服用中藥成藥者，較未使用中藥成藥者，其危害商數高出 3.57 ± 0.21 倍至 31.5 ±6.62 倍，以明目用藥 31.5 ±6.62 倍最高。

英文摘要

Chinese medicine plays an important role in therapeutic behavior of Chinese. Accompanying by the Chinese medicine and Western medicine’s cooperation and some clinical trials, Chinese herbal medicine was proofed have efficiency in preventing cancer and evaluating immune response and increasing acceptable worldwide. Due to the heavy metal poisoning within the Chinese herbal medicine make some people doubt the safety of them and do not use them. Thus, this study attempts to measure heavy metal concentration in Chinese herbal medicine over-the-counter drugs, to analyse users’ motives and intensions, to assess the risk of health, and provide reference to regulatory authority. Data were collected through questionnaire in Miao-Li county, sampling, and laboratory measurement of the metal concentration in Chinese herbal medicine over-the-counter drugs. The analyzed results show: (1) the Arsenic concentration in 48 samples all lower than 5 ppm which

the Singapore government regulated in drug. (2) the lead concentration in 48 samples all lower than 10 ppm which the current standard in China botanical drug. (3) the cadmium concentration in 48 samples lower than 0.3 ppm which the current standard in China botanical drug except Shen Zhong Su Wu Wan and Ba Wei Di Huang Wan . (4) the mercury concentration in 48 samples have 18 samples higher than 5 ppm which the Singapore government regulated in drug. In risk assessment aspect: (1) Target Hazard Quotient (THQ): when calculated by all sample, the value is lower than the acceptable value 1, but when calculated by therapeutic function, the over-the-counter drugs used for arthritis and vision its lead's THQ values are higher than the acceptable value 1, and the over-the-counter drugs used for anemia and women diseases its mercury's THQ values are higher than the acceptable value 1. (2) Target Cancer Risk (TR): The TR of arsenic in over-the-counter drugs taken for various diseases in the long term (30 years) are over 3.57 ± 0.21-31.50 ± 6.62 times than the acceptable value, especially the drugs used for vision.