

槐花散治療痔瘡之臨床試驗研究

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【摘要】 中藥槐花的乾燥花朵與果實在中國, 日本和韓國用於治療痔瘡出血。本研究為一項前瞻性、雙盲、隨機、安慰劑對照之臨床試驗, 來評估槐花散之臨床療效和安全性。主要以臨床效果, 症狀評分, 不良反應的發生率為觀察指標, 以評估中藥槐花散治療痔瘡的效果。研究結果表明, 80%患者的主要症狀被緩解, 而 20%患者在治療後 7 天內改善。與常規治療比較顯示, 72.2%患者的症狀改善, 而 5.5%患者的症狀持續無改善。經過 14 天, 治療組中 91.6%的患者已無症狀, 而在對照組的 18.8%的患者仍表現出殘餘症狀。兩組之間的主要區別是在對痔瘡出血狀況有顯著改善 ($p < 0.01$)。其他症狀, 如疼痛, 瘙癢和腫脹感迅速消失。無論是否使用槐花散, 可能由於患者坐浴與排便習慣的衛教改善, 痔瘡症狀顯著恢復。結果顯示, 中國傳統草藥槐花散有效和安全。比常規治療相比, 可以更迅速地降低出血症狀。目前的研究結果將提供臨床醫師治療有症狀的痔瘡患者時之用藥參考。

【Abstract】 Dried flowers and buds of *Sophora japonica* (Huaihua) are used as medicine in China, Japan, and Korea for treating bleeding haemorrhoids and haematemesis. The study compared the clinical efficacy and safety of *Sophora* flower formula with placebo in the conservative treatment of symptomatic haemorrhoids. The study was designed as a prospective, double-blind, randomized, and placebo-controlled trial. The clinical effective rate, symptom score, incidence of important clinical events were defined as the observation indices to evaluate the effect of *Sophora* flower formula. Analytical results showed that 80% of the patients' major symptoms were eliminated, while 20% improved within 7 days after the treatment. Comparison with the conventional treatment showed that 72.2% of the patients' symptoms improved, while 5.5% of the patients' symptoms persisted without improvement. After 14 days, 91.6% patients in the treatment group became asymptomatic, whereas 18.8% patients in the control group exhibited residual symptoms. The major difference between the 2 groups was significant improvement in the haemorrhage condition of the haemorrhoids ($p < 0.01$). Other symptoms such as pain, itchiness, and swelling sensation disappeared rapidly. As the bowel habits improved and the patients took sitz baths, the symptoms improved drastically, regardless of the use of the *Sophora* flower formula. The traditional Chinese herbal formula of *Sophora* flower is clinically effective and safe for the treatment of symptomatic haemorrhoids. Haemorrhaging can be reduced more rapidly by using this formula than by conventional treatments. It is anticipated that the present study results will provide a clinical reference for physicians when prescribing medication for patients with symptomatic haemorrhoids.