

广痛消泡沫气雾剂对肛门直肠疾病止痛作用的临床研究

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摘要 为研制适用于肛门直肠急慢性疼痛病症或肛肠手术后疼痛的止痛剂,开发出纯中药广痛消泡沫气雾剂,是中药的新剂型。经临床观察并与西药消炎痛栓剂比较,止痛效果好,平均起效时间快(7.05 ± 4.87 分钟),维持时间长(5.65 ± 1.71 小时),明显优于消炎痛栓剂。同时该药剂对出血、排便困难、局部血栓、水肿、充血,均有较好的缓解作用。

主题词 肛门疾病/中医药疗法 直肠疾病/中医药疗法 止痛药(中药)/投药和剂量

广痛消泡沫气雾剂是由纯中药组成的新型肠道外用止痛药物,经临床观察对肛肠手术后疼痛及肛门直肠急慢性疼痛病症有良好的止痛效果,且止痛时间较长,现报告如下。

1 病例选择

本组病例均为诊断明确的血栓外痔、肛裂、嵌顿痔术后引起的疼痛和炎性外痔、肛窦炎、肛痛、肛瘘等疾病引起的疼痛患者;年龄 18 岁以上,性别不限,能合作评价疼痛程度者;心肝肾功能无严重障碍者;受试者术前 8 小时及治疗过程中未用过其它镇痛药物者。

2 一般资料

可评价病例共 181 例,门诊 94 例,病房 87 例。其中男 96 例,女 85 例。平均年龄 45 岁。181 例患者随机分为两组,广痛消气雾剂组(简称治疗组)118 例,消炎痛栓组(简称对照组)63 例。

3 治疗方法

治疗组用广痛消泡沫气雾剂,该药由延胡索、厚朴、细辛、当归、白芍、黄柏、茜草、薄荷组成,经提取有效成分,制成泡沫气雾剂(由广安门医院制剂室提供)。本品经肛门直肠给药,治疗时将气雾剂罐喷管插入肛门内 5~8cm,再将

气罐倒置,按压喷射按钮 3 秒,每日 2 次,每次需间隔 6~8 小时,连续给药 3 日。

对照组予西药消炎痛(吲哚美辛)栓剂,经肛门直肠给药,每次 1 粒(100mg),每日 2 次,每次间隔 6~8 小时,连续给药 3 日。

4 疗效分析

4.1 用药前后疼痛级别确定标准:采用医生判定和患者自身判定疼痛程度二种方法。

医生判定:0 级:无痛,评为 0 分;Ⅰ级:轻度疼痛(轻度),肛门部疼痛反应轻,尚可忍受,正常生活、睡眠不受干扰。局部触压反应轻微,能坐椅。无显著情绪变化,评为 1 分;Ⅱ级:较明显疼痛(中度),肛门部疼痛反应较著,不能忍受,要求用镇痛药,正常生活及睡眠受干扰,有情绪改变,易怒烦躁,肛门触压痛反应明显,轻触即痛,评为 2 分;Ⅲ级:剧烈疼痛(重度),难以忍受,疼痛反应剧烈,严重干扰正常生活及睡眠,必须使用镇痛药;被动或强迫体位出现,行走、坐位、排便及咳嗽均受限或加剧,伴有植物神经功能紊乱者,评为 3 分。

自身判定:在医生指导下患者进行判定。采用目测划线分级法(VAS)。小于 1 为微痛,1~4 为轻度,4~7 为中度,7~9 为重度,大于 10 为极度疼痛。

给药后记录起效时间,每 5 分钟为 1 个间隔;药物维持时间从药物起效后,以 1 小时为 1 个间隔。

4.2 治疗前后两组疼痛变化比较:表 1 示,经治疗后治疗组和对照组疼痛程度均有明显好转(P 均 <0.05),治疗组多数病例已无疼痛,而对照组仅 1/3 病例无疼痛。

4.3 治疗后两组疼痛评分比较:治疗组治疗前平均分为 2.28 ± 0.56 分,治疗后降至 0.29 ± 0.73 分($\bar{X} \pm S$, 以下同),下降幅度为 87.3%

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($P < 0.01$); 对照组治疗后平均分为 2.30 ± 0.61 分, 治疗后降至 1.05 ± 0.58 分, 下降幅度为 54.3% ($P < 0.01$)。两组治疗后评分比较, 差异有极显著性 ($P < 0.01$)。

4.4 治疗前后两组 VAS 测试比较: 表 2 示, 治疗前后两组患者以 VAS 自身判定疼痛情况, 治疗后治疗组无痛者占大多数, 而对照组仅 1/4 左右病例感到无疼痛。

表 1 两组治疗前后疼痛程度变化比较

分组	治疗前				治疗后			
	0	I	II	III	0	I	II	III
治疗组	0	13	64	41	81	33	4	0
对照组	0	6	38	19	21	26	13	3

表 2 两组 VAS 测试结果比较

分组	治疗前				治疗后			
	0	1~4	5~7	8~10	0	1~4	5~7	8~10
治疗组	0	14	64	40	83	28	7	0
对照组	0	5	36	22	15	23	24	1

4.5 两组药物起效时间比较: 记录后统计, 治疗组药物起效时间平均为 7.05 ± 4.87 分钟, 对照组为 20.28 ± 8.51 分钟, 两组比较差异有极显著性 ($P < 0.01$)。

4.6 两组药物维持时间比较: 经统计, 治疗组药物维持时间为 5.65 ± 1.71 小时, 对照组为 2.54 ± 1.34 小时, 两组比较差异有极显著性 ($P < 0.01$)。

4.7 治疗后两组症状体征变化情况: 治疗组用药后除有明显止痛效果外, 多数患者便血症状亦消失, 排便困难减轻, 局部视诊见血栓、水肿、

充血明显减轻或消失; 对照组用药后便血、排便困难改善不明显, 局部血栓、水肿、充血亦有减轻或消失, 但血栓改善不如治疗组。

5 讨论

广痛消泡沫气雾剂属中药新剂型, 尚未见国内有此方面的报道。自 1992 年研制以来, 经临床试验、毒理药效试验及药理工艺制备研究, 取得了有效的实验资料, 证实该药的镇痛效果, 同时观察到该药有凝血止血及抗炎消肿作用。临床观察证实, 在肛门直肠局部应用, 其特点为起效快, 维持时间较长, 无明显毒副作用及不良反应, 安全可靠。泡沫型气雾剂经肛门直肠应用, 通过皮肤粘膜吸收, 发挥有效作用。由于泡沫逐渐崩解, 占有相当大的体积与管腔组织面接触, 所以在药物浓度相同时, 泡沫制剂的用量较少而能发挥更大作用, 并能减少因药物吸收而可能产生的副作用。泡沫气雾剂还具有粘弹性、扩展性、持续缓慢渗透性和柔软舒适感, 使疗效提高, 药效维持长, 患者易于接受。泡沫型气雾剂的优势是软膏、灌肠剂、粉剂、栓剂等无法相比的。

广痛消经 5 年多的临床观察, 可用于肛门、会阴、盆腔、直肠、乙状结肠各种急慢性疼痛病症, 尤其对常见的血栓外痔、嵌顿痔、炎性外痔、内痔出血坠痛、静脉曲张性混合痔、肛裂、肛瘘及各种肛门直肠手术或其它方法治疗后引起的疼痛、便血、排便困难有良好疗效。

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ABSTRACTS OF ORIGINAL ARTICLES

Investigation and Comparative Study on the Annual Rhythm of Rheumatic Pain. Report of 1607 Cases

Li Shao

Comparative study were made on the annual rhythm in terms of sorts, regions, and sex in 1607 cases. It was found that, under the condition of common nature of basic model for rhythm, there was a definite difference in the rhythm of incidence between various sorts of pain, while that for the rhythm of pain attacks was weaker, that for the rhythm of regional rhythm was even more weaker, whereas it revealed no differences in terms of sexual rhythm.

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Key words: rheumatic diseased epidemiology pain/therapeutics

(Original article on page 408)

Clinical Study on the Analgesic Action of Guangtongxiao Foam — aerosol in Anal — rectal Diseases

Zhao Baoming, Shi Zhaoqi, Jing Jianzhong et al.

To explore effective analgesics for pain in the anal — rectal region post operation, a pure TCM remedy, Guangtongxiao foam aerosol was developed which is a new therapeutic form. Through clinical observation and comparison between it and indomethacin, a western suppository, it yielded a satisfactory result, with a rapid analgesic effect ($7.05 \pm 0.87 \text{ min}$), longer analgesic duration ($5.65 \pm 1.71 \text{ hr}$), markedly superior to the controlled western remedy. Moreover, it also yielded mitigating actions on bleeding, difficult defecation, local thrombosis, edema, and congestion.

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Key words: Anal disease/TCM therapy rectal disease/TCM therapy analgesic (traditional Chinese drug)/administration of drug and its dosage

(Original article on page 412)

Influence of Huangqi Wuwu Decoction on Many Plasmal Proteins in 70 Cases of Chronic Cor Pulmonale

Che Hongzhu, Luo Kaili

By adopting the single method of immune agar —

diffusion, the values of 12 items of plasmal protein in 70 cases of chronic cor pulmonale receiving Huangqi Wuwu Decoction therapy were examined before and after the treatment with another 70 cases suffering the same disorder and receiving no TCM treatment as the control group. Results showed that the clinically effective rate of the treatment group was 90%, while that of the control group, 75.7%, with significant difference ($P < 0.05$). In the treatment group, the prealbumin, transferrin, fibrin conjugated protein were all markedly increased before and after the treatment; the C reactive protein, ceruloplasmin, α — antitrypsin, α — acid glycoprotein were all markedly decreased. ($P < 0.001$). While in the control group, only ceruloplasmin, C — reactive protein were lowered markedly, indicating that the Decoction can raise the therapeutic effectiveness of cor pulmonale, regulate the metabolic imbalance of plasmal protein and improve the living quality of the patients.

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Key words: Cor pulmonale/TCM therapy cor pulmonale/blood Huangqi Wuwu Decoction/therapeutic application

(Original article on page 414)

Protective Action of Kidney — tonics on Oto — intoxication of Gentamycin in Guinea Pig

Xu Shaoqin, Tan Jingshu, Zeng Xingsan

By adopting induction — electricity threshold of brain stem, counting of hairy cells in cochlear membrane, and electromicroscopic exam of ultra microscopic structure before and after the administration of the drug, it was shown that kidney tonics can protect the hairy cells, effectively resist the increased of hearing threshold caused by gentamycin, demonstrating that such kidney tonics can protect the cochlear structure and function, minimize the oto — toxicity of gentamycin.

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Key words: deafness/chemical induction deafness/TCM therapy kidney tonics/therapeutic application

(Original article on page 430)