

芪竭颗粒治疗慢性盆腔炎 102 例临床观察

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摘要 目的:观察芪竭颗粒治疗慢性盆腔炎的疗效。方法:以芪竭颗粒治疗慢性盆腔炎 102 例,并与妇科千金片治疗 70 例作对照,观察疗效、T 淋巴细胞亚群及血液流变学指标。结果:治疗组临床总有效率为 96.08%,对照组为 84.29%,组间差异有显著性($P<0.01$);服用芪竭颗粒也能改善血粘度,对 T 淋巴细胞亚群有调节作用,治疗前后比较差异有显著性($P<0.05$ 或 $P<0.01$)。结论:慢性盆腔炎的中医本质可能是气虚血瘀,芪竭颗粒治疗慢性盆腔炎具有良好疗效,其机理可能与改善血液循环,促进炎症吸收和调节免疫机能,减少复发有关。

主题词 子宫附件炎/中医药疗法 @ 芪竭颗粒剂

慢性盆腔炎易于复发,发病率有逐年上升趋势,我们根据中医传统理论,结合慢性盆腔炎的证治规律,提出了从气虚血瘀论治的新思路,取得了较好的临床疗效。近年来,我们将验方改制成颗粒剂,为证实其疗效,我们开展了以下临床研究。

1 临床资料

1.1 中医诊断标准:参照全国高等中医院校现行妇科学教材制定。气虚血瘀证:反复小腹或少腹疼痛,腰骶酸痛,神疲乏力,劳累后疼痛易复发,带下量多色白或黄,舌质淡或暗,苔薄,脉沉细或涩。

1.2 西医诊断标准:参照《中药新药临床研究指导原则》^[1]制订。症状:下腹及腰痛,下腹坠胀,腰骶部疼痛,常在劳累、性交后、排便时加重,可伴有低热,月经量多,不孕等。妇科检查:子宫常见后倾,活动受限或粘连固定,输卵管发炎时,在子宫一侧或两侧可触及条索状物并有轻度压痛,盆腔结缔组织发炎时,子宫一侧或两侧有片状增厚压痛或在盆腔一侧或两侧扪及包块。

1.3 病情评分标准:参照《中药新药临床研究指导原则》^[1]制订。子宫活动受限、压痛,5 分;输卵管呈条索状压痛,5 分;子宫一侧或两侧片状增厚、压痛,5 分;下腹、腰部酸痛下坠,3 分;带下增多,1 分;低热疲乏,1 分;经期腹痛,1 分;病程每增加 1 年加 0.5 分。分级标准:重度,积分在 15 分以上;中度,积分在 10~15 分;轻度,积分在 5~9 分。

1.4 一般资料:全部病例均系 1996 年 9 月~2001 年 9 月本院门诊及病房的患者。172 例患者中,门诊 112

例,住院 60 例,随机分为治疗组 102 例,对照组 70 例,治疗组年龄 20~48 岁,平均 34.8 ± 6.93 岁;病程 0.5~11 年,平均 4.6 ± 1.79 年;病情评分 6~22 分,平均 14.32 ± 3.37 岁;对照组年龄 23~47 岁,平均 33.7 ± 6.24 岁;病程 0.5~9 年,平均 4.4 ± 2.09 年;病情评分 6~22 分,平均 14.41 ± 3.29 分。两组患者的年龄、病情程度及病程均具有可比性($P>0.05$)。

2 治疗及观察方法

2.1 治疗方法:治疗组选用芪竭颗粒(药物组成:黄芪、血竭、当归、桂枝、茯苓、红藤、败酱草、熟地黄、没药、芍药、甘草等,每包 3g,相当于含生药 24.5g,由江阴天江制药厂生产,批号 981018)口服,每次 2 包,每日 2 次,温水冲服;对照组选用妇科千金片(主要成分金樱根、千斤拔、当归等,批号 9812004,由湖南株洲制药厂生产,每片 0.32g,相当于原生药 3.4g),每次 6 片,每日 3 次,温水吞服。均连服 2 个月为 1 个疗程。

2.2 观察指标:疗效性观察:临床症状、妇科检查、T 淋巴细胞亚群(由美国库尔特公司生产的 EPICS-XL 型流式细胞仪测定)、血液流变学指标(由北京普利生精密仪器研制中心生产的 LBY-N5 型旋转式血液粘度计测定)。安全性观察:一般体检项目、血、尿、大便常规检查,肝肾功能检查,心电图检查:治疗组做 20 例,用药前后各检测 1 次,以观察有无毒副作用。

2.3 统计学处理:计数资料采用 χ^2 检验,计量资料用 t 检验。

3 治疗结果

3.1 疗效判断标准:参照《中药新药临床研究指导原则》^[1]。痊愈:症状、体征消失,妇科检查正常,积分为 0 分;显效:症状消失,妇科检查有显著改善,治疗后比治疗前积分降低 2/3 以上。有效:症状、体征及检查均有减轻,治疗后比治疗前降低 1/3 以上。无效:治疗后无改善。

3.2 治疗前后两组临床疗效比较:治疗组 102 例,临床痊愈 14 例,显效 51 例,有效 33 例,无效 4 例,总有效率为 96.08%,总显效率为 63.73%;对照组 70 例,临床痊愈 3 例,显效 21 例,有效 35 例,无效 11 例,总有效率为 84.29%,总显效率为 34.29%。治疗组明显优于对照组($P<0.01$)。

3.3 治疗前后两组症状积分比较:治疗组 102 例,治

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表1 两组治疗前后T淋巴细胞亚群变化的比较($\bar{x} \pm s$)

组别		例数	T(%)	NK(%)	CD ₄ (%)	CD ₈ (%)	CD ₄ /CD ₈
治疗组	治疗前	40	69.3±5.98	8.08±2.1	36.8±5.1	28.6±5.5	1.29±0.28
	治疗后	35	72.6±6.06 [*]	11.8±2.92 ^{**}	42.8±6.2 ^{**}	23.5±2.3 ^{**}	1.68±0.24 ^{**}
对照组	治疗前	30	70.4±6.12	8.15±2.3	37.2±3.1	27.9±2.5	1.32±0.27
	治疗后	26	69.8±5.94	9.13±2.45	38.8±2.9	26.9±4.6	1.44±0.24

与本组治疗前比较, * $P < 0.05$, ** $P < 0.01$

表2 两组治疗前后血液流变学指标变化比较($\bar{x} \pm s$)

组别		例数	全血粘度(mPa·s)		血浆粘度值(mPa·s)	红细胞聚集指数
			高切	低切		
治疗组	治疗前	40	2.88±0.40	12.76±1.23	1.76±0.39	5.08±0.62
	治疗后	40	1.93±0.41*	10.67±0.84*△	1.32±0.40*	3.56±0.67*△
对照组	治疗前	30	2.84±0.38	12.64±1.35	1.69±0.32	5.17±0.60
	治疗后	30	2.01±0.39*	11.72±1.01*	1.44±0.34*	4.66±0.59*

与本组治疗前比较, * $P < 0.01$; 与对照组治疗后比较, △ $P < 0.01$

疗前积分 14.32 ± 3.37 , 治疗后积分 4.47 ± 1.18 ; 对照组治疗前积分 14.41 ± 3.29 , 治疗后积分 7.59 ± 2.42 , 与治疗前比较, 两组差异均有显著性($P < 0.01$); 治疗后两组间比较差异亦有显著性, 治疗组优于对照组($P < 0.01$)。

3.4 治疗前后T淋巴细胞亚群测定值比较: 表1示, 治疗组选择了40例进行T淋巴细胞亚群测定, 35例在疗程结束后复查, 与治疗前比较差异有显著性($P < 0.05$ 或 $P < 0.01$), 对照组选择了30例进行T淋巴细胞亚群测定, 26例在疗程结束后复查, 治疗前后比较, 差异无显著性($P > 0.05$), 治疗组疗效明显优于对照组。

3.5 治疗前后血液流变学指标测定比较: 表2示, 治疗组观察了40例患者的血液流变学指标, 治疗前后比较差异均有显著性($P < 0.01$), 对照组观察了30例患者, 治疗前后比较差异也有显著性($P < 0.01$), 但治疗组在低切粘度、红细胞聚集指数二项与对照组比较差异有显著性($P < 0.01$), 治疗组疗效优于对照组。

3.6 安全性评价: 经观察服用芪竭颗粒未见毒副作用和不良反应。

4 讨论

慢性盆腔炎是妇科常见病、难治病, 有缠绵不愈、易于复发的特点, 是国内外妇科治疗中的一大难题^[2]。盆腔感染多为需氧菌和厌氧菌的混合感染^[3], 名中医何少山根据几十年的临床经验, 以“久病多虚, 久病多瘀”的理论为依据, 提出慢性盆腔炎应抓住虚、瘀、寒、湿为侧重点, 以气虚血瘀论治为辨证思路^[4], 总结以益气健脾、温经散瘀为主的芪竭颗粒治疗本病, 取得了良好效果。T淋巴细胞是正常机体免疫功能最重要的一大细胞群, 各亚群的数量和功能发生异常时, 就会导致

病理变化。本研究通过流式细胞术检测不同的亚群并计算出它们相互的比例, 结果表明芪竭颗粒能明显提高NK细胞及CD₄细胞的活性, 改善CD₄/CD₈比例, 从而调节免疫功能, 从根本上预防其反复发作。芪竭颗粒集益气养血、温经化瘀、利湿解毒于一方, 以黄芪、血竭为主药, 扶正无留寇之虑, 祛邪无伤正之忧^[5], 配桂枝、芍药、当归温经养血活血, 促进血液循环, 有助于炎性渗出的吸收^[6], 加红藤、制大黄、败酱草利湿解毒祛瘀, 消除致病原^[7], 茯苓助黄芪健脾利水湿, 没药伍血竭消瘀解痛, 甘草配芍药缓急止痛, 全方选药精当, 从临床观察看, 既能减轻临床症状及体征, 又能起到免疫调节功能, 提高免疫力, 同时亦改善了血液流变学, 促进炎性病灶的消退及增生性病变的软化和吸收, 使整体功能与局部病变明显改善, 充分发挥中医整体调节的特色, 真正起到扶正祛邪之作用^[8]。本剂型为颗粒剂, 便于服用, 是治疗慢性盆腔炎一种安全、有效的药物, 值得进一步研究及开发。

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ABSTRACTS FROM ORIGINAL ARTICLES

Clinical study on Jian Shen Li Shui No. 1 for treatment of 60 cases of cerebral edema at acute stage due to acute cerebral hemorrhage

Liu Tai, Gan Zhaoru, Lu Hui, et al.

Objective: To investigate the therapeutic effect and safety of Jian Shen Li Shui No. 1 for treatment of acute cerebral hemorrhage.

Methods: The patients enrolled were randomly divided into 3 groups. The group A were treated with Jian Shen Li Shui No. 1, the group B with Xing Nao Xiao Zhong Capsules and the group C with 20% mannitol. Symptoms and signs, changes of urine volume, quality of life, routine examination of blood, urine and feces, function of liver and kidney, electrocardiogram, blood lipid, sugar, electrolytes, rheological changes were observed.

Results: The total effective rate in the group A was superior to that in the group B ($P < 0.01$), with no significant difference between the group A and C ($P > 0.05$); while the cured and markedly effective rate in the group A was better than that in the group C ($P < 0.05$). The group A in the effect on life quality was better than the group B and C ($P < 0.01$ or $P < 0.05$).

Conclusion: Jian Shen Li Shui No. 1 is effective and safe for treatment of acute cerebral hemorrhage, and it can raise life quality of the patient and decrease the disabled rate.

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Key words: Cerebral hemorrhage/TCM therapy

(Original article on page 108)

Clinical observation on 102 cases of chronic pelvic inflammation treated with Qi Jie Granules

Zhang Qin, He Jialin, He Shaoshan, et al.

Objective: To investigate the therapeutic effect of Qi Jie Granules on chronic pelvic inflammation. **Methods:** 102 cases of chronic pelvic inflammation were treated by Qi Jie Granules, and 70 cases were treated with Fu Ke Qian Jin Tablets as control.

Their therapeutic effects, subgroups of T-lymphocytes and hemorheological indexes were investigated. **Results:** The total clinical effective rate was 96.08% in the treatment group and 84.29% in the control group, with a significant difference between the two groups ($P < 0.01$). Also, the Qi Jie Granules could improve blood viscosity and regulate subgroups of T-lymphocytes before and after treatment ($P < 0.05$ or $P < 0.01$). **Conclusion:** TCM essence of chronic pelvic inflammation is possibly qi-deficiency and blood stasis, and Qi Jie Granules has a good therapeutic effect on chronic pelvic inflammation, which is possibly related with improvement of blood circulation, promotion of inflammation absorption, regulation of immunological function, and reducing relapse.

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Key words: Adnexitis/TCM therapy @Qi Jie Granules

(Original article on page 121)

Effect of Fu Zheng Hua Yu Recipe on hepatic sinusoid capillarization in the rat of dimethyl nitrosamine-induced hepatic fibrosis

Lu Xiong, Liu Ping, Liu Chenghai, et al.

Objective: To investigate the effect of Fu Zheng Hua Yu-319 Recipe on hepatic sinusoid capillarization in the rat of hepatic fibrogenesis. **Methods:** Hepatic fibrosis model rats were induced by intraperitoneal injection of dimethyl nitrosamine (DMN), thrice a week for 4 weeks, and they were divided into the treatment group which were treated with Fu Zheng Hua Yu-319 Recipe for 4 weeks, and the model control group. Serum and hepatic tissue were taken for examination of pathohistology, microstructure by electron microscopy, immunohistochemistry, and hydroxyproline content in the liver tissue and hepatic function. **Results:** In the normal group, peripheral cytoplasm of endothelial cells in the hepatic sinusoid is very thin with a lot of small fenestra, and no basement membrane under endothelium was found. In the model group, crookedness and stricture of the hepatic sinusoid were found, and the fenestra in cytoplasm of the endothelial cell reduced or disappeared with obvious basement membrane, and hemorrhage necrosis in the liver tissue could be found, with a great proliferation of connective tissue in the portal area, and fibrous septum extended towards into the lobuli, the content of hydroxyproline (HYP) in the liver tissue increased significantly. The VIII factor-related antigen, α -actin of smooth muscle, LM and type IV collagen positive staining on the hepatic sinusoid wall increased significantly with a wider range as compared with the normal rat. In the treatment group, the extents of crookedness and stricture of hepatic sinusoid and reduction and disappearance of endothelial fenestra were lower, with thinner or discontinuous basement membrane, and a part of hepatic sinusoid construction approached to normal, and degeneration and necrosis of hepatic cells were mild and fibrous septum in the liver tissue decreased significantly, and HYP content decreased significantly ($P < 0.05$), and the VIII factor-related antigen, α -actin of smooth muscle, LM and type IV collagen positive staining on the hepatic sinusoid walls weakened significantly, with significant decrease in the image analysis results of distribution area ($P < 0.05$). **Conclusion:** The Fu Zheng Hua Yu Recipe can effectively inhibit experimental hepatic fibrosis and sinusoid capillarization.

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Key words: Hepatic fibrosis/TCM therapy @Fu Zheng Hua Yu Recipe hepatic fibrosis/pathophysiology

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