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紫星口服液治疗晚期肺癌的临床观察

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内容提要　本组报告了单纯服用紫星口服液治疗19例晚期肺癌患者，其近期临床疗效观察证明紫星口服液可明显抑制肺癌的发展，提高机体的免疫功能。癌块缩小25%以上客观有效率63.3%，总缓解率36.9%，治疗后一年生存率为47.3%，中位生存期在10个月左右，其中腺癌为10个月，鳞癌为12个月。为延长患者生存期，提高生存质量开辟了一条有效的治疗方法。

关键词　紫星口服液　肺癌　NK细胞　白细胞介素-2

我科从1988年5月至1990年5月应用长春中医学院中医研究所研制的紫星口服液治疗晚期肺癌19例，取得明显的疗效，现报告如下。

临床资料

本组19例患者中，男15例，女4例，年龄37～75岁，50～70岁为15例，占79%。痰检癌细胞，阳性14例；剖胸术取病理证实4例；胸水癌细胞阳性1例。病理类型：鳞癌12例，腺癌7例。右肺13例，左肺6例，中央型14例，周围型5例。来院就诊时咳嗽、咳痰带血16例，胸痛12例，呼吸困难6例，上腔静脉综合征1例。纵隔内淋巴结转移者11例，颈及锁骨上淋巴结转移者2例，胸水1例，脑转移者1例。根据新的国际肺癌分期法[1]，19例患者中，Ⅲ期15例，Ⅳ期4例。

治疗方法

紫星口服液系中药紫草提取物紫草萘醌色素(Red Naphthoquinone Pigment)、人参皂甙等配伍制成的胶体型液体药剂，紫草萘醌色素谓之君药，每毫升含1.0 mg，呈紫红色澄明液体。每瓶250 ml，每日用药剂量分别为0.4 mg/kg、0.6mg/kg、0.75 mg/kg，每日3次，饭前口服。本组病例治疗前未经任何方法治疗，且治疗期间均不配合其它疗法。全部病例均连续治疗一个月，胸片、免疫各项指标检测采样均在治疗前及用药一个月时。本组19例患者预计近期不会危及生命，并能坚持治疗一个月以上。由于恶性肿瘤自发消退十分罕见，故没有设对照组，仅进行治疗前后自身对照观察药物对瘤体的治疗作用。

结　果

一、对患者生存质量和主要症状的影响：患者服用紫星口服液后生存质量明显提高，16例患者食欲明显转好，体重增加0.5～2.0 kg，Karnofsky评分平均提高20分。由肿瘤引起的主要症状包括咳嗽、咳痰带血消失11例，好转5例，胸痛消失8例，好转4例，呼吸困难消失5例，好转1例，1例上腔静脉综合征消失。

二、疗效评定标准：根据1988年卫生部药政局制定的抗癌药物临床研究指导原则疗效标准，分为5个等级。癌灶计算方法：以肿块的最大径及其最大垂直径的乘积来计算，并以完全缓解(CR)、部分缓解(PR)计算总缓解率，并加上好转(MR)计算有效率。完全缓解(CR)：所有可见病变完全消失并至少维持4周以上。部分缓解(PR)：肿块病灶的最大径及最大垂直径的乘积减少50%以上，肺不张全部复张，并维持4周以上。好转(MR)：肿瘤病灶的两径乘积缩小25%以上，但小于50%，无新病灶出现。稳定(SD)：肿瘤病灶的两径乘积缩

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小＜25％或增大＜25％，无新病灶出现。病变进展（PD）：肿瘤病灶的两径乘积增大＞25%，或出现新病灶。

本组经紫星口服液治疗后CR1例(5.3%)，PR 6例(31.6%)，MR 5例(26.3%)，SD 7例(36.9%)，PD为0。总缓解率：CR+PR=36.9%，有效率：CR+PR+MR=63.3%。

三、病理类型的分析：本组19例中鳞癌12例，CR 1例，PR 4例，总缓解率41.7%。腺癌7例，PR 2例，总缓解率28.6％。

四、治疗效果与君药紫草萘醌色素剂量的分析：本组19例中，每日用0.4 mg/kg 6例，总缓解率为50%；每日用0.6mg/kg 11例，总缓解率为36.4%；每日用0.75 mg/kg 2例，总缓解率为0。以上提示每日用0.4 mg/kg～0.6mg/kg为“适宜”剂量范围。

五、治疗前后细胞免疫功能、肿瘤标记物(CEA)检测结果的比较，见附表。

附表 治疗前后各项检测指标结果($\bar{x}\pm S$)

	例数	治疗前	治疗后
淋　　转(%)	19	19.74±1.45	30.36±1.99*
NK细胞活性(%)	19	18.86±1.32	27.17±1.59*
白细胞介素-2(%)	19	24.48±1.76	37.01±2.41*
E玫瑰花结形成率(%)	5	33.8 ±10.6	58.8 ±6.45**
CEA (μg/ml)	19	22.84±5.91	12.50±2.08**

注：与治疗前比较　*$P<0.001$；**$P<0.05$

六、副作用：本组病例服用紫星口服液无不适症状及毒性反应，末梢血象、心、肝、肾等脏器功能检测结果未见异常改变。

七、随访情况：本组病例随访最短3个月，最长20个月，平均11.4个月，随访率100％。其中带瘤生存9例，死亡10例。治疗后生存一年以上者9例，占47.3%。中位生存期在10个月左右，其中腺癌为10个月，鳞癌为12个月。

讨　论

原发性支气管肺癌是严重危害人类生命最常见的恶性肿瘤之一。由于全身状况不佳，往往不能耐受化学药物治疗，多数病例化疗后很快导致衰竭，况且腺癌对化疗药物不敏感，治疗上更为困难。我们依照扶正祛邪中医理论，研制新的中药方剂紫星口服液，在增强机体抗病能力的情况下，抑制癌瘤的增长，直至控制。临床实践证实可以达到延缓生命的目的。紫星口服液的主要有效成分为紫草，属清热解毒、补中益气、凉血类中药。经实验研究证实，对多种实验性肿瘤的生长及转移有抑制作用，而且具有不同程度的免疫调节功能，且无毒性[3,4]。特别是晚期肺癌，免疫功能一般均为低下，尤其是NK细胞和IL-2活性，经给紫星口服液治疗后，多数患者不仅全身情况有明显好转，而且细胞免疫水平均有显著提高，使异常的免疫状态得到纠正，从而提高了机体免疫功能，而延长患者的生命。本组病例经紫口星服液治疗后取得瘤块缩小25%以上的客观有效率63.3%，取得总缓解率36.9％，治疗后一年生存率为47.3％。中位生存期在10个月左右，其中腺癌为10个月，鳞癌为12个月。由以上结果看：我们认为紫星口服液治疗肺癌的作用机理可能在于：增强荷瘤机体自身的免疫监视功能，尤其是NK细胞、IL-2等活性细胞对瘤细胞的吞噬杀伤活性。

通过临床实践观察，紫星口服液在调动机体的抗病能力，延长生存期，提高生存质量等方面有着独特的长处，因此，在制定合理的综合治疗方案中，充分发挥中西医各种治疗方法在疾病过程中各阶段的作用，取长补短，努力做到既能最大限度地抑制或杀灭癌细胞（祛邪），又能提高机体抗病的能力（扶正），这样对肺癌的治疗可望得到进一步提高。所以我们认为紫星口服液是治疗晚期肺癌有较好疗效的药物，预想手术切除术前术后应用此药更会有效，有待于进一步研究。

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groups: Fang-Gan mixture (FGM) group, levamisole group, and the control group. The results showed that the total effective rate of FGM was 98.7%, which was more effective than the levamisole group. Its effective rate still reached 90.9% after 1 month of stopping treatment, and compared with the treatment period, there were no significant differences *($P > 0.05$)*. There were three parts of changes on clinical menifestation after patients using FGM: (1)The occurrence times reduced obviously; (2)the course of disease shortened obviously; (3)syndrome of patients relieved obviously. FGM was also more effective than the levamisole group in relieving symptoms and signs *($P < 0.05$)*. Both the FGM and the levamisole groups could increase the body immunity function. After treatment both of salivary sIgA and PHA skin test were higher than before treatment *($P < 0.05$)*.

Key Words repeated infantile respiratory tract infection, salivary IgA, phytohemagglutinin

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Comparison Study of Various TCM Therapy in Acute Phase of Cor Pulmonal

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This article is a retrospective summary of 419 cases of acute phase of cor pumonal from 1978 to 1989. These patients were divided into 4 groups by various TCM therapy, as a part of whole treatment combining TCM with the western medicine. They were (1) clearing the lung heat and eliminating the phlegm; (2) clearing the lung heat, tonifying the Qi(气) and activating the blood; (3) clearing the lung heat, tonifying the Qi and nourishing the Yin(阴); (4) clearing the lung heat, nourishing the Yin, tonifying the Qi and activating the blood. Under a similar condition, comparing the effects of the 4 various therapies in clinical efficacy and blood gas analysis, the authors found that the 4th therapy was the best among the 4 groups. According to the relation of modern pharmacology study of each single therapy, the authors explored the principle of clearing the lung heat, nourishing the Yin, tonifying the Qi and activating the blood therapy. The authors held that the therapy is a better one to treat many pathological changes in acute phase of cor pulmonal.

Key Words cor pulmonal, traditional Chinese medicine therapy, clearing the lung heat, nourishing the Yin and tonifying the Qi, activating the blood

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Clinical Trial on the Effects of Shikonin Mixture on Later Stage Lung Cancer

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The Shikonin mixture was used for 19 cases of later-stage lung cancer who were not the candidates for operation, radiotherapy and chemotherapy. The clinical observation showed that Shikonin mixture could inhibit the growth of lung cancer and improve the immune function of the body. The tumors were reduced over 25% in diameter. The effective rate was 63.3%, remission rate 36.9%, survival rate of one year 47.3%. The intermedium survival period was about 10 months, including adenocarcinoma 10 months, squamous carcinoma 12 months. After treatment the life quality of patients were greatly improved. The patients got better appetite and their body weights were increased. They could manage themselves in daily life. The Karnofsky scores were enhanced by 20. The authors also observed that Shikonin mixture could relieve such symptoms as cough, bloody sputum and chest pain caused by lung cancer. The levels of cells and interleukin-2 were increased *($P < 0.001$)*. It had no harmful effects on peripheral blood picture, heart, kidney and liver. Shikonin mixture is safe and effective for later-stage cancer.

Key Words Shikonin mixture, lung cancer, NK cell, interleukin-2

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