

艾迪注射液联合TP方案治疗非小细胞肺癌的临床观察

施子夏^{1*}, 张劲^{1#}, 张兵兵¹, 马铮²(1.重庆市第三人民医院胸外科, 重庆 400014; 2.第三军医大学大坪医院胸外科, 重庆 400015)

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摘要 目的:观察艾迪注射液联合TP方案治疗非小细胞肺癌的临床疗效及安全性。方法:将62例非小细胞肺癌患者按随机数字表法分为对照组和观察组,各31例。对照组患者单独采用TP方案治疗,观察组患者在对照组治疗基础上加用艾迪注射液40 ml溶于500 ml 0.9%氯化钠注射液中静脉滴注。两组患者均以21 d为1个周期,共治疗4个周期。比较两组患者治疗前后的炎症因子水平及治疗后的生存质量、近期疗效、满意度和毒副反应发生情况。结果:治疗后,两组患者各炎症因子水平均明显低于治疗前,且观察组患者明显低于对照组,差异均有统计学意义($P<0.05$)。观察组患者生存质量评分和近期疗效的有效率(分别为80.64%、83.87%)均明显高于对照组(分别为32.25%、64.52%),差异均有统计学意义($P<0.05$)。观察组患者的满意度(96.77%)明显高于对照组(77.42%);血小板下降、白细胞下降、肝功能异常的发生率明显低于对照组,差异均有统计学意义($P<0.05$)。结论:艾迪注射液联合TP方案对非小细胞肺癌的疗效显著、毒副反应小,且有利于降低炎症因子水平,提高患者的免疫功能及生存质量。

关键词 非小细胞肺癌;TP化疗方案;艾迪注射液;疗效;炎症因子;毒副反应

Clinical Observation of Aidi Injection Combined with TP Regimen in the Treatment of Non-small Cell Lung Cancer

SHI Zixia¹, ZHANG Jin¹, ZHANG Bingbing¹, MA Zheng²(1.Dept. of Thoracic Surgery, the Third People's Hospital of Chongqing, Chongqing 400014, China; 2.Dept. of Thoracic Surgery, Daping Hospital of Third Military Medical University, Chongqing 400015, China)

ABSTRACT OBJECTIVE: To observe the clinical efficacy and safety of Aidi injection combined with TP regimen in the treatment of non-small cell lung cancer. METHODS: 62 patients with non-small cell lung cancer were randomly divided into control group and observation group, 31 cases in each group. Control group received TP regimen alone, observation group additionally received 40 ml Aidi injection, dissolved in 500 ml 0.9% Sodium chloride injection by intravenous infusion. 21 d was a treatment course, and it lasted 4 courses. The level of inflammatory cytokines before and after treatment and post-treatment quality of life, short-term efficacy, patients' satisfaction and toxicity reactions in 2 groups were compared. RESULTS: After treatment, the level of inflammatory cytokines in 2 groups were significantly lower than before, and observation group was lower than control group, the differences were statistically significant ($P<0.05$). The effective rate of life quality (80.64%) and short-term efficacy (83.87%) in observation group significant were higher than control group (32.25%, 64.52%, respectively), the differences were statistically significant ($P<0.05$). Satisfaction degree (96.77%) in observation group was significantly higher than control group (77.42%); and the incidences of thrombocytopenia, leukopenia, abnormal liver function were significantly lower than control group, the differences were statistically significant ($P<0.05$). CONCLUSIONS: Aidi injection combined with TP regimen shows good efficacy and little toxicity in the treatment of non-small cell lung cancer, and it helps to reduce the level of inflammatory cytokines in patients, improving immune function and the quality of life of patients.

KEYWORDS Non-small cell lung cancer; TP chemotherapy regimen; Aidi injection; Efficacy; Inflammatory cytokines; Toxicity reaction

目前,肺癌已成为危害人类健康的主要恶性肿瘤之一,其中非小细胞肺癌(NSCLC)是临床上非常常见的病症,且其发病率、病死率均呈逐年上升的趋势^[1]。由于大多数NSCLC患者在确诊时已是中晚期,失去了手术治疗的最佳机会,故此阶段主要的治疗方法是化疗,但其容易对患者免疫功能及生存质量造成影响^[2]。本研究中,笔者对初诊为NSCLC的患者进行化疗时加用了艾迪注射液,疗效显著,现报道如下。

1 资料与方法

1.1 纳入与排除标准

纳入标准:(1)经组织学或细胞学确诊为NSCLC的患者;(2)卡氏(KPS)评分^[3]≥60分;(3)预计生存期>3个月;(4)肝

肾功能及血常规正常;(5)治疗依从性较好;(6)患者或其家属签署知情同意书。

排除标准:(1)有严重慢性病史且需长期服药者;(2)有精神病史或神经性病变者;(3)已接受相关治疗并可能对观测指标造成影响者;(4)有严重心、肝、肾损害而影响代谢者。

1.2 研究对象

本研究方案经医院医学伦理委员会审核批准后,选取2013年6月—2015年6月在重庆市第三人民医院进行治疗的62例NSCLC患者,按随机数字表法分为对照组和观察组,各31例。其中,观察组男性17例,女性14例;年龄48~77岁,平均年龄(55.7±6.5)岁;体质量60~81 kg,平均体质量(63.8±4.6)kg;病理部位:鳞癌8例,腺癌12例,腺鳞癌11例;临床分期:Ⅲ期9例,Ⅳ期22例。对照组男性18例,女性13例;年龄46~73岁,平均年龄(52.7±5.3)岁;体质量59~79 kg,平均体质量(59.5±4.3)kg;病理部位:鳞癌10例,腺癌13例,腺鳞癌8

* 主治医师。研究方向:胸外科学。电话:023-63511031。E-mail:232142438@qq.com

通信作者:副主任医。研究方向:胸外科学。电话:023-63511031。E-mail:Zj950825@sina.com

例;临床分期:Ⅲ期11例,Ⅳ期20例。两组患者的性别、年龄、体质量、病理部位和临床分期等基本资料比较,差异均无统计学意义($P>0.05$),具有可比性。

1.3 治疗方法

对照组患者单独采用TP化疗方案:在询问患者有无过敏史并查看白细胞及血小板数据之后,在化疗前12、6 h分别给予醋酸地塞米松片(天津天药业股份有限公司,批准文号:国药准字H12020686,批号:20120621,规格:0.75 mg)10.50 mg口服;化疗前60 min给予盐酸苯海拉明片(山西太原药业有限公司,批准文号:国药准字H14022436,批号:20110121,规格:25 mg)50 mg口服;化疗前30 min给予西咪替丁胶囊(广东恒健制药有限公司,批准文号:国药准字H44020623,批号:20101205,规格:0.2 g)0.2 g口服。给予紫杉醇注射液(扬子江药业集团有限公司,批准文号:国药准字H20053001,批号:20110918,规格:5 ml:30 mg)175 mg/m²静脉滴注,3 h滴完,d1;之后给予注射用顺铂(齐鲁制药有限公司,批准文号:国药准字H37021358,批号:20110928,规格:10 mg)25 mg/m²静脉滴注,d1~3。最后对患者行常规的利尿、止吐及水化等治疗。观察组患者在对照组治疗的基础上加用艾迪注射液(贵州益佰制药股份有限公司,批准文号:国药准字Z52020236,批号:20120727,规格:10 ml/支)40 ml溶于500 ml 0.9%氯化钠注射液中静脉滴注,qd。两组患者均以21 d为1个周期,共治疗4个周期。

1.4 观察指标及疗效评定标准

1.4.1 治疗前后各炎症因子水平 分别于治疗前和治疗3个周期后采集患者静脉血3 ml,以离心半径为8 cm、转速为100 r/min离心10 min,采用酶联免疫吸附法(ELISA)对白细胞介素(IL)6、IL-10、肿瘤坏死因子(TNF) α 水平进行测定;另采用美国贝克曼库尔特公司生产的EPICS ALTR型流式细胞仪对患者外周血T淋巴细胞亚群(CD4⁺、CD4⁺/CD8⁺)进行测定。试剂盒均购自上海基免生物技术有限公司。

1.4.2 生存质量 依据KPS评分标准^[3],分别于治疗前和治疗

3个周期后对患者的生存质量进行评分。显著:治疗后比治疗前增加20分;改善:治疗后比治疗前增加10分;稳定:治疗前后无明显变化;减退:治疗后比治疗前减少10分及以上。有效率=(显著例数+改善例数)/总例数 \times 100%。

1.4.3 近期疗效 治疗3个周期后进行评定。依据世界卫生组织(WHO)实体瘤近期疗效评价标准^[4],将疗效分为完全缓解(CR):患者可见肿瘤完全消失,且维持1个月及以上;部分缓解(PR):患者的肿瘤病灶体积减少50%以上,未发现新的肿瘤病灶,且维持1个月及以上;无变化(NC):患者的肿瘤病灶体积减少50%以下或增大25%以下,未发现新的肿瘤病灶,且维持1个月及以上;进展(PD):患者的肿瘤病灶体积增大25%以上,发现新的肿瘤病灶。有效率=(CR例数+PR例数)/总例数 \times 100%。

1.4.4 满意度 办理出院时,由患者或其家属填写满意度调查表,对疗效满意度进行评定,分为满意、基本满意、不满意。满意度=(满意例数+基本满意例数)/总例数 \times 100%。

1.4.5 毒副反应 治疗4个周期后进行评定。依据WHO抗癌药物常见毒副反应分级标准^[5],统计两组患者血小板下降、白细胞下降、肝功能异常0~Ⅳ级的发生例数,计算毒副反应总发生率。

1.5 统计学方法

采用SPSS 14.0软件对数据进行统计分析。各炎症因子水平等计量资料以 $\bar{x} \pm s$ 表示,采用 t 检验;近期疗效与生存质量等计数资料采用 χ^2 检验;毒副反应与满意度等计数资料采用秩和检验。 $P<0.05$ 表示差异有统计学意义。

2 结果

2.1 两组患者治疗前后各炎症因子水平比较

治疗前,两组患者各炎症因子水平(T淋巴细胞中CD4⁺T细胞比例、CD4⁺/CD8⁺比率及IL-6、IL-10、TNF- α 浓度)比较,差异均无统计学意义($P>0.05$)。治疗后,两组患者各炎症因子水平均明显低于治疗前,且观察组患者明显低于对照组,差异均有统计学意义($P<0.05$)。两组患者治疗前后各炎症因子水平比较见表1。

表1 两组患者治疗前后各炎症因子水平比较($\bar{x} \pm s$)

Tab 1 Comparison of the level of inflammatory cytokines between 2 groups before and after treatment($\bar{x} \pm s$)

组别	<i>n</i>	时期	CD4 ⁺ , %	CD4 ⁺ /CD8 ⁺	IL-6, μ mol/L	IL-10, μ mol/L	TNF- α , μ mol/L
观察组	31	治疗前	52.53 \pm 10.21	1.94 \pm 0.71	6.29 \pm 2.43	3.81 \pm 1.45	22.09 \pm 7.58
		治疗后	40.33 \pm 10.19*	1.41 \pm 0.65*	2.25 \pm 1.44*	1.23 \pm 1.43*	7.66 \pm 2.43*
对照组	31	治疗前	51.62 \pm 11.20	1.90 \pm 0.65	5.93 \pm 2.12	3.95 \pm 1.32	22.20 \pm 8.41
		治疗后	45.50 \pm 10.29*	1.71 \pm 0.31*	4.22 \pm 1.09*	2.86 \pm 1.11*	12.33 \pm 3.50*
治疗后组间比较		<i>t</i>	2.574 4	3.004 0	7.865 9	6.493 1	7.903 5
		<i>P</i>	0.011 5	0.003 4	<0.000 1	<0.000 1	<0.000 1

注:与治疗前比较,* $P<0.05$

Note: vs. before treatment,* $P<0.05$

2.2 两组患者生存质量比较

治疗后,观察组患者生存质量改善的有效率为80.64%,明显高于对照组的32.25%,差异有统计学意义($P<0.05$)。两组患者生存质量比较见表2。

表2 两组患者生存质量比较[例(%)]

Tab 2 Comparison of life quality between 2 groups [case (%)]

组别	<i>n</i>	显著	改善	稳定	减退	总有效
观察组	31	9(29.03)	16(51.61)	4(12.90)	2(6.45)	25(80.64)
对照组	31	3(9.67)	7(22.58)	13(41.94)	8(25.81)	10(32.25)
χ^2			3.572 3			4.209 7
<i>P</i>			0.000 4			0.040 2

2.3 两组患者近期疗效比较

治疗后,观察组患者的有效率为83.87%,明显高于对照组的64.52%,差异有统计学意义($P<0.05$)。两组患者近期疗效比较见表3。

表3 两组患者近期疗效比较[例(%)]

Tab 3 Comparison of short-term efficacy between 2 groups [case (%)]

组别	<i>n</i>	CR	PR	NC	PD	总有效
观察组	31	20(64.52)	6(19.35)	5(16.13)	0	26(83.87)
对照组	31	3(9.68)	17(54.84)	5(16.13)	6(19.35)	20(64.52)
χ^2		9.547 1	3.902 7	4.652 8	5.513 5	3.510 1
<i>P</i>		0.002 0	0.048 2	0.031 0	0.018 9	0.000 4

前列地尔联合丹参酮Ⅱ_A治疗早期慢性肾病的临床观察

杨蓉*,常佳丽(中航工业363医院消化内分泌肾内科,成都 610041)

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摘要 目的:观察前列地尔联合丹参酮Ⅱ_A治疗早期慢性肾病(ECKD)的临床疗效及安全性。方法:选取ECKD患者138例,按随机数字表法分为A、B、C组,各46例。在常规治疗的基础上,A组患者给予丹参酮Ⅱ_A磺酸钠注射液40 mg加入0.9%氯化钠注射液250 ml中,ivgtt,qd+前列地尔注射液10 μg加入0.9%氯化钠注射液100 ml中,ivgtt,qd;B组患者给予同等剂量前列地尔注射液治疗;C组患者给予同等剂量丹参酮Ⅱ_A磺酸钠注射液治疗。3组患者均治疗14 d。观察3组患者临床疗效及治疗前后实验室检查指标[24 h尿蛋白定量、血肌酐(SCr)、总胆固醇(TC)、三酰甘油(TG)、尿素氮(BUN)、尿酸(UA)],并比较不良反应发生情况。结果:A组患者临床总有效率为97.83%,显著高于B组的80.43%及C组的76.09%,差异均有统计学意义($P<0.05$)。3组患者治疗前24 h尿蛋白定量、SCr、TC、TG、BUN及UA的水平比较,差异均无统计学意义($P>0.05$);治疗后,3组患者上述指标均显著降低,且A组显著低于B组和C组,差异均有统计学意义($P<0.05$)。A组患者不良反应发生率为10.87%,与B组的6.52%及C组的8.70%比较,差异无统计学意义($P>0.05$)。结论:前列地尔联合丹参酮Ⅱ_A治疗ECKD疗效显著,能明显改善患者的肾功能,且安全性较好。

关键词 前列地尔;丹参酮Ⅱ_A;早期慢性肾病;临床疗效

Clinical Observation of Alprostadil Combined with Tanshinone II_A in the Treatment of Early Chronic Kidney Disease

YANG Rong, CHANG Jiali (Dept. of Digestive Endocrine and Nephrology, AVIC 363 Hospital, Chengdu 610041, China)

ABSTRACT OBJECTIVE: To observe the efficacy and safety of alprostadil combined with tanshinone II_A in the treatment of patients with early chronic kidney disease (ECKD). METHODS: 138 ECKD patients were randomly divided into group A, group B and group C, 46 cases in each group. On the basis of conventional treatment, group A received 40 mg Tanshinone II_A sodium sulfonate injection, adding into 250 ml 0.9% Sodium chloride solution, ivgtt, qd+10 μg Alprostadil injection, adding into 100 ml 0.9% Sodium chloride solution, ivgtt, qd; group B received the same dose with Alprostadil injection; group C received the same dose with Tanshinone II_A sodium sulfonate injection. All patients were treated for 14 d. Clinical efficacy, laboratory indexes [24 h urine protein, serum creatinine (SCr), total cholesterol (TC), triglyceride (TG), blood urea nitrogen (BUN), uric acid (UA)] in 3 groups before and after treatment were observed, and the incidence of adverse reactions was compared. RESULTS: The total effective rate in group A was 97.83%, which was significantly higher than group B (80.43%) and group C (76.09%), the differences were statistically significant ($P<0.05$). Before treatment, there were no significant differences in 24 h urine protein, SCr, TC, TG, BUN and UA among 3 groups ($P>0.05$); after treatment, all above-mentioned indexes significantly reduced, and group A was lower than group B and group C, the differences were statistically significant ($P<0.05$). There was no significant difference in the incidence of adverse reactions among group A (10.87%), group B (6.52%) and group C (8.70%) ($P>0.05$). CONCLUSIONS: Alprostadil combined with tanshinone II_A shows good efficacy in the treatment of ECKD, it can improve renal function in patients with good safety.

KEYWORDS Alprostadil; Tanshinone II_A; Early chronic kidney disease; Clinical efficacy

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* 主治医师。研究方向:肾内科。电话:028-61810452。E-mail:29478497@qq.com

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(编辑:胡晓霖)