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参芪扶正注射液联合多西他赛对乳腺癌患者外周血象、免疫功能及血清肿瘤标志物的影响*

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摘要 目的:观察参芪扶正注射液联合多西他赛对乳腺癌患者外周血象、免疫功能及血清肿瘤标志物的影响。**方法:**选取 2018 年 1 月~2019 年 12 月我院收治的 64 例乳腺癌患者,根据信封抽签法将患者分为对照组($n=32$,多西他赛治疗)和研究组($n=32$,参芪扶正注射液联合多西他赛治疗)。对比两组疗效,对比两组治疗前、治疗 2 个疗程后的外周血象、免疫功能及血清肿瘤标志物,记录两组治疗期间不良反应情况。**结果:**比较两组不良反应无差异($P>0.05$)。治疗 2 个疗程后,对照组的总有效率为 43.75%(14/32),研究组的总有效率为 68.75%(22/32),研究组的总有效率高于对照组($P<0.05$)。治疗 2 个疗程后,两组血红蛋白、血小板、白细胞水平均较治疗前下降,但研究组高于对照组($P<0.05$)。两组 $CD3^+$ 、 $CD4^+$ 、 $CD8^+$ 、 $CD80$ 、 $CD86$ 水平均较治疗前下降,但研究组高于对照组($P<0.05$)。治疗 2 个疗程后,两组癌胚抗原(CEA)、糖蛋白 125(CA125)、糖蛋白 153(CA153)水平均较治疗前下降,且研究组低于对照组($P<0.05$)。**结论:**参芪扶正注射液联合多西他赛治疗乳腺癌患者,可有效减少肿瘤标志物分泌,抑制肿瘤生长,减轻机体免疫抑制,改善外周血象,且安全可靠。

关键词:参芪扶正注射液;多西他赛;乳腺癌;外周血象;免疫功能;肿瘤标志物

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Effect of Shenqi Fuzheng Injection Combined with Docetaxel on Peripheral Blood Picture, Immune Function and Serum Tumor Markers in Patients with Breast Cancer*

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ABSTRACT Objective: To observe the effect of Shenqi Fuzheng injection combined with docetaxel on peripheral blood picture, immune function and serum tumor markers in patients with breast cancer. **Methods:** 64 patients with breast cancer who were admitted to our hospital from January 2018 to December 2019 were selected, they were divided into control group ($n=32$, docetaxel treatment) and study group ($n=32$, Shenqi Fuzheng injection combined with docetaxel treatment) according to the envelope drawing method. The curative effect of the two groups was compared, the peripheral blood picture, immune function and serum tumor markers before treatment and 2 courses after treatment were compared, the adverse reactions of the two groups during the treatment were recorded. **Results:** There was no difference in adverse reactions between the two groups ($P>0.05$). 2 courses after treatment, total effective rate of control group was 43.75% (14/32), total effective rate of study group was 68.75% (22/32), the total effective rate of the study group was higher than control group ($P<0.05$). 2 courses after treatment, hemoglobin, platelets and white blood cells levels of the two groups decreased compared with those before treatment, but the study group was higher than the control group ($P<0.05$). The levels of $CD3^+$, $CD4^+$ 、 $CD8^+$, $CD80$, $CD86$ of the two groups were lower than those of before treatment, but the study group was higher than control group ($P<0.05$). 2 courses after treatment, levels of carcinoembryonic antigen (CEA), glycoprotein 125 (CA125), glycoprotein 153 (CA153) of the two groups decreased compared with those of before treatment, and the study group was lower than the control group ($P<0.05$). **Conclusion:** Shenqi Fuzheng injection combined with docetaxel in the treatment of breast cancer patients, can effectively reduce the secretion of tumor markers, inhibit tumor growth, reduce immune suppression, improve peripheral blood picture, and which is safe and reliable.

Key words: Shenqi Fuzheng injection; Docetaxel; Breast cancer; Peripheral blood picture; Immune function; Tumor markers

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前言

乳腺癌是临床上常见的恶性肿瘤,患病后可表现出消瘦、乏力与食欲减退等症状,该病可由激素、遗传、饮食与环境等内外因素共同引发,患者以 40~60 岁的女性为主,是引起妇女死亡的主要原因之一^[1-3]。临床上治疗乳腺癌一般采用手术治疗,并于术后接受化疗以巩固治疗效果、延长生存期。由于乳腺癌患者的全身机能状况随着病情的进展已出现减退,故而化疗药物往往需要同时具备有效性和安全性^[4]。多西他赛为紫杉醇类抗肿瘤药,可在诸多恶性肿瘤如膀胱癌、乳腺癌、肺癌中发挥较大的功效^[5,6]。参芪扶正注射液具有益气扶正的功效,能提高气虚者的免疫能力,可辅助癌症治疗,并提高疗效与生存率^[7,8]。本研究通过参芪扶正注射液联合多西他赛治疗乳腺癌患者,探讨其对患者外周血象、免疫功能及血清肿瘤标志物的影响,整理如下。

1 资料与方法

1.1 临床资料

选取我院于 2018 年 1 月~2019 年 12 月收治的乳腺癌患者 64 例,纳入标准:(1)参考《中国常见恶性肿瘤诊断规范》^[9];(2)经乳头溢液、影像学检查以及乳腺结节穿刺活检术确诊者;(3)辩证分型为肝郁痰凝证^[10];(4)意识清楚,各项生命体征平稳者;(5)Karnofsky 评分超过 60 分^[11];(6)所有患者纳入研究前均未接受任何放疗或化疗;(7)患者及其家属知情且签定同意书;(8)经化验血常规和肝肾功能检测均无异常。排除标准:(1)年老体弱且伴有严重内脏器质性病变患者;(2)合并严重感染、免疫性、内分泌疾病者;(3)预计生存期<3 个月者;(4)对本研究用药禁忌者;(5)精神疾病或神志不清者;(6)合并凝血功能障碍者。本研究经我院医学伦理委员会批准。根据信封抽签法将患者分为对照组(n=32)和研究组(n=32)。其中对照组年龄 46~82 岁,平均(63.49±4.82)岁;TNM 分期 II 期 18 例、III 期 14 例;病理类型:管状癌 12 例,髓样癌 14 例,浸润性小叶癌 6 例;卡氏评分(KPS)61~88 分,平均(73.37±3.44)分;体质量指数 20~28 kg/m²,平均(23.61±0.98)kg/m²。研究组年龄 45~80 岁,平均(63.21±5.36)岁;TNM 分期 II 期 16 例、III 期 16 例;病理类型:管状癌 11 例,髓样癌 13 例,浸润性小叶癌 8 例;卡氏评分(KPS)63~90 分,平均(73.98±3.45)分;体质量指数 20~27

kg/m²,平均(23.27±1.05)kg/m²。对比两组一般资料无差异($P>0.05$),均衡可比。

1.2 方法

对照组给予多西他赛(规格:多西他赛注射液;0.5 mL:20 mg,多西他赛注射液专用溶剂:1.5 mL,瀚晖制药有限公司,国药准字:H20093520)治疗,d1 给药,剂量:75 mg/m²,静脉滴注 1 h,以生理盐水稀释。滴注前 3d 开始肌注地塞米松(规格:2 mg(以地塞米松磷酸钠计),沈阳光大制药有限公司,国药准字 H20052186),8 mg/次,每 12 h 注射 1 次;西咪替丁(吉林康乃尔药业有限公司,国药准字 H20030645,规格:100 mL;西咪替丁 0.2g 与氯化钠 0.9g),300 mg/次,每 10 h 注射 1 次。在此基础上,研究组联合参芪扶正注射液(规格:每瓶装 250 mL,丽珠集团利民制药厂,国药准字 Z19990065)治疗,静脉滴注,1 次/d。两组都治疗 2 个疗程(1 疗程=3 周)。

1.3 指标观察

于空腹状态,提取两组治疗前、治疗 2 个疗程后的清晨静脉血 6 mL,分为 2 管,1 管采用贝克曼 DXC800 全自动生化分析仪检测外周血象:血红蛋白、血小板、白细胞以及免疫功能指标:淋巴细胞亚群:CD3⁺、CD4⁺/CD8⁺以及树突状细胞指标:CD80、CD86。另 1 管经常规离心处理,应用酶联免疫法对测出血清肿瘤标志物:糖蛋白 125(CA125)、癌胚抗原(CEA)、糖蛋白 153(CA153),按试剂盒(武汉默沙克生物科技有限公司)说明书严格操作。

1.4 疗效判定

总有效率=部分缓解率+完全缓解率。病灶完全消失,最少持续 4 周(完全缓解);肿瘤大小至少缩小 50%,持续 4 周以上(部分缓解);瘤体缩小<50%或增大<25%(疾病稳定);瘤体增大至少 25%或病理检查出新病灶(疾病进展)^[12]。

1.5 统计学方法

采用 SPSS26.0 进行数据分析,计数资料以(%)的形式表示,行卡方检验;计量资料以($\bar{x} \pm s$)的形式表示,行 t 检验。检验标准设置为 $\alpha=0.05$, $P<0.05$ 为差异有统计学意义。

2 结果

2.1 疗效

治疗 2 个疗程后,对照组总有效率为 43.75%(14/32),低于研究组的 68.75%(22/32)($P<0.05$),见表 1。

表 1 两组临床疗效比较 [例(%)]

Table 1 Comparison of clinical efficacy between the two groups [n(%)]

Groups	Complete remission	Partial remission	Stable disease	Progression of disease	Total effective rate
Control group(n=32)	4(12.50)	10(31.25)	10(31.25)	8(25.00)	14(43.75)
Study group(n=32)	7(21.88)	15(46.88)	8(25.00)	2(6.25)	22(68.75)
χ^2					4.063
P					0.044

2.2 外周血象指标

两组治疗前外周血象指标比较无差异($P>0.05$);两组治疗 2 个疗程后外周血象指标比治疗前更低,而研究组相比对照组更高($P<0.05$),见表 2。

2.3 免疫功能指标

两组治疗前 CD3⁺、CD4⁺/CD8⁺、CD80、CD86 比较无差异($P>0.05$);两组治疗 2 个疗程后 CD3⁺、CD4⁺/CD8⁺、CD80、CD86 均较治疗前下降,而研究组较对照组高($P<0.05$),见表 3。

表 2 两组外周血象指标比较($\bar{x} \pm s$)

Table 2 Comparison of peripheral blood index between the two groups ($\bar{x} \pm s$)

Groups	Hemoglobin(g/L)		Platelets ($\times 10^9/L$)		White blood cells($\times 10^9/L$)	
	Before treatment	2 courses after treatment	Before treatment	2 courses after treatment	Before treatment	2 courses after treatment
Control group(n=32)	126.56 $\pm$ 27.13	92.54 $\pm$ 17.62 ^a	174.42 $\pm$ 28.53	117.64 $\pm$ 27.84 ^a	8.21 $\pm$ 2.25	4.38 $\pm$ 1.09 ^a
Study group(n=32)	125.21 $\pm$ 19.07	106.38 $\pm$ 18.92 ^a	175.05 $\pm$ 27.50	141.22 $\pm$ 23.62 ^a	8.16 $\pm$ 2.11	6.65 $\pm$ 1.98 ^a
t	0.230	3.028	0.090	3.653	0.092	5.681
P	0.819	0.004	0.929	0.001	0.927	0.000

Note: compared with before treatment, ^a $P < 0.05$.

表 3 两组免疫功能指标比较($\bar{x} \pm s$)

Table 3 Comparison of immune function indexes between the two groups ($\bar{x} \pm s$)

Groups	CD3 ⁺ (%)		CD4 ⁺ (/CD8)		CD80(%)		CD86(%)	
	Before treatment	2 courses after treatment	Before treatment	2 courses after treatment	Before treatment	2 courses after treatment	Before treatment	2 courses after treatment
Control group (n=32)	43.71 $\pm$ 7.52	31.72 $\pm$ 6.69 ^a	1.33 $\pm$ 0.28	0.86 $\pm$ 0.23 ^a	8.81 $\pm$ 0.31	6.17 $\pm$ 0.48 ^a	38.42 $\pm$ 5.49	29.34 $\pm$ 5.67 ^a
Study group (n=32)	43.38 $\pm$ 6.40	37.73 $\pm$ 5.71 ^a	1.29 $\pm$ 0.34	1.07 $\pm$ 0.24 ^a	8.84 $\pm$ 0.34	7.14 $\pm$ 0.57 ^a	38.53 $\pm$ 4.38	34.09 $\pm$ 7.53 ^a
t	0.189	3.865	0.514	4.382	0.369	7.363	0.089	6.746
P	0.851	0.000	0.609	0.000	0.714	0.000	0.930	0.000

Note: compared with before treatment, ^a $P < 0.05$.

2.4 血清肿瘤标志物

两组治疗前比较血清肿瘤标志物无差异($P > 0.05$);治疗 2 个疗程后,两组 CA125、CEA、CA153 较治疗前降低,且研究组

相对对照组更低($P < 0.05$),见表 4。

2.5 不良反应

比较两组不良反应无差异($\chi^2 = 0.674, P = 0.412$),见表 5。

表 4 两组血清肿瘤标志物比较($\bar{x} \pm s$)

Table 4 Comparison of serum tumor markers between the two groups ($\bar{x} \pm s$)

Groups	CEA(ng/mL)		CA125(U/mL)		CA153(U/mL)	
	Before treatment	2 courses after treatment	Before treatment	2 courses after treatment	Before treatment	2 courses after treatment
Control group(n=32)	17.81 $\pm$ 2.28	14.87 $\pm$ 1.34 ^a	71.25 $\pm$ 5.24	58.37 $\pm$ 6.32 ^a	161.40 $\pm$ 19.26	125.15 $\pm$ 14.29 ^a
Study group(n=32)	17.76 $\pm$ 2.53	9.72 $\pm$ 1.23 ^a	71.47 $\pm$ 6.28	35.28 $\pm$ 5.46 ^a	160.92 $\pm$ 23.24	93.41 $\pm$ 15.32 ^a
t	0.083	16.016	0.152	15.639	0.090	8.570
P	0.948	0.000	0.880	0.000	0.929	0.00

Note: compared with before treatment, ^a $P < 0.05$.

表 5 两组不良反应发生率比较 [例(%)]

Table 5 Comparison of the incidence of adverse reactions between the two groups [n(%)]

Groups	Myelosuppression	Nausea and vomiting	Liver function lesion	Leukopenia	Total Incidence
Control group(n=32)	3(9.38)	4(12.50)	2(6.25)	2(6.25)	11(34.38)
Study group(n=32)	2(6.25)	2(6.25)	2(6.25)	2(6.25)	8(25.00)
χ^2					0.674
P					0.412

3 讨论

近年来乳腺癌发病率呈不断上升的趋势,该病症状较多,

常见有消瘦、乳头溢液、食欲减退、皮肤异变等,严重危害患者身心健康^[13,14]。现临床有关乳腺癌的治疗手段有手术和化疗等,部分患者由于各种原因失去了手术治疗的最佳时机,此时化疗

成了他们的首选治疗方案,通过辅助化疗,可有效延缓肿瘤恶化^[15,16]。多西他赛是目前治疗乳腺癌的一线药物,主要药物原理为:使体液内微管蛋白发生聚合的速度加快,从而发挥干扰解聚反应的功能,进而使癌细胞的分裂得到抑制,使癌细胞中止于有丝分裂期,导致肿瘤细胞无法持续增殖,从而发挥抗肿瘤作用^[17,18]。然而已知的化疗法都会损害机体正常组织,在杀伤癌细胞的同时也使人体受伤,引起患者出现不良反应,如精神不振、浑身乏力、食欲减退、干呕等,对患者的免疫系统造成极大损伤,导致患者无法耐受化疗方案,无法继续治疗甚至危及患者生命^[19,20]。医学的进步使得乳腺癌的治疗观念得到改善,综合治疗时代的到来,使乳腺癌防治进入新阶段,中医学在癌症的临床治疗中的位置逐渐凸显,其以提高免疫力、扶正培本、改善内环境为基本原则。参芪扶正注射液在临床上常用于癌症的辅助治疗,主要成分为黄芪、党参,具有改善免疫功能、固本培元的作用^[21]。

本次研究结果显示,研究组的总有效率高于对照组,表明参芪扶正注射液联合多西他赛治疗乳腺癌患者,疗效肯定。在中医药中,黄芪补气、利水消肿,党参补气养血、健脾和胃,参芪扶正注射液联合了两味药的优点,以达改善患者身弱体虚之症、增强患者免疫力的功效,从而发挥出了更强大的抗肿瘤效果^[22]。患者在化疗后可出现血红蛋白、血小板、白细胞减少的情况,影响机体造血功能,导致机体处于血虚状态,不利于患者治疗耐受^[23,24]。CD3⁺、CD4⁺/CD8⁺是临床常见的免疫功能指标,其中CD4⁺/CD8⁺比例失衡提示机体免疫功能出现紊乱^[25,26]。此外,树突状细胞在抗癌免疫反应中,参与了抗原呈递过程,具有重要作用,CD80和CD86是表达于树突状细胞表面的一对偶联的重要共刺激蛋白分子,CD80与CD86必须与T细胞表面处在休眠期的CD28分子相结合后,才能活化T细胞,进而诱导T细胞的增殖和分化,因此在抗癌免疫反应中,增加树突状细胞的能力也能发挥很大功效^[27,28]。CA125是卵巢癌的特异性标志物,在部分乳腺癌患者中会出现相应的水平升高现象;CEA在多种癌症如胃癌、肺癌、乳腺癌中均呈现高表达;CA153则在45%的乳腺癌患者以及部分消化道肿瘤、卵巢癌患者体内发生升高。研究还显示参芪扶正注射液联合多西他赛治疗可有效减少肿瘤标志物分泌,促进外周血象改善,减轻机体免疫抑制。现代药理研究结果显示^[29],参芪扶正注射液具有抗炎的作用,可以抑制炎症因子分泌,提高多种与抗肿瘤相关的免疫因子,减弱患者免疫功能的抑制作用,有效改善患者外周血象。其中党参可以活化自然杀伤细胞及T细胞亚群,增强它们对癌细胞的杀伤能力,还能提升机体内皮网状系统的防御功能,并强化单核-巨噬细胞的抗癌作用^[30]。黄芪可调节细胞免疫,扩张血管,保护骨髓造血,保护胃肠道及心脏功能^[31]。另本研究结果显示该联合治疗方案安全性较好,不会降低患者耐受。

综上所述,参芪扶正注射液联合多西他赛治疗乳腺癌患者,可有效减少肿瘤标志物分泌,抑制肿瘤生长,减轻机体免疫抑制,改善外周血象,且安全可靠。

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