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## 丹红注射液对急性心肌梗死患者经皮冠状动脉介入治疗后血清IL-6和IL-17水平的影响

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**[摘要]** 目的: 探讨丹红注射液对急性心肌梗死(acute myocardial infarction, AMI)患者经皮冠状动脉介入治疗(percutaneous coronary intervention, PCI)后血清IL-6和IL-17水平的影响。方法: 选取2014年6月至2016年1月在第四军医大学唐都医院心内科急诊PCI术后的120例ST抬高型心肌梗死(ST-elevation myocardial infarction, STEMI)患者, 随机分为对照组和研究组, 每组各60例。两组均给予常规治疗, 而研究组则在常规治疗基础上给予静脉滴注丹红注射液治疗。观察两组临床症状和体征的改善情况、心电图的恢复情况及不良反应发生情况, 评估两组的临床疗效。ELISA测定两组患者治疗前和治疗3, 7 d后血清IL-6和IL-17的水平。比较两组治疗前后左室射血分数和心肌梗死面积的变化。随访6个月, 观察两组患者主要不良心血管事件(major adverse cardiovascular events, MACE)的发生情况。结果: 研究组治疗的总有效率为90.00%, 显著高于对照组的76.67%, 两组间差异有统计学意义( $P<0.05$ ); 研究组治疗3, 7 d后血清IL-6水平分别为 $(56.38\pm10.75)$  ng/mL,  $(42.52\pm8.14)$  ng/mL, 均显著低于对照组的 $(62.73\pm12.08)$  ng/mL,  $(51.65\pm9.78)$  ng/mL, 两组间差异有统计学意义( $P<0.05$ ); 研究组治疗3, 7 d后血清IL-17水平分别为 $(28.73\pm5.68)$  ng/mL,  $(22.54\pm4.55)$  ng/mL, 均显著低于对照组的 $(34.39\pm6.21)$  ng/mL和 $(29.82\pm5.74)$  ng/mL, 两组间差异有统计学意义( $P<0.05$ ); 研究组治疗后的LVEF为 $54.72\%\pm5.64\%$ , 显著高于对照组的 $49.38\%\pm4.57\%$ , 两组间差异有统计学意义( $P<0.05$ ); 研究组治疗后的心肌梗死面积为 $10.64\%\pm4.38\%$ , 明显低于对照组的 $16.74\%\pm5.49\%$ , 两组间差异有统计学意义( $P<0.05$ )。结论: 丹红注射液可有效降低PCI术后STEMI患者血清IL-6和IL-17的水平, 改善患者心功能, 缩小心肌梗死面积, 降低MACE的发生率, 安全有效, 值得应用于临床。

**[关键词]** 丹红注射液; 急性心肌梗死; 经皮冠状动脉介入; IL-6; IL-17

## Effect of Danhong injection on the serum IL-6 and IL-7 level in patients with acute myocardial infarction after percutaneous coronary intervention

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**Abstract** **Objective:** To discuss the impact of Danhong injection on the serum IL-6 and IL-17 level in patients with acute myocardial infarction after percutaneous coronary intervention (PCI). **Methods:** A total of 120 patients with ST-segment elevation myocardial infarction (STEMI) after PCI from June 2014 to January 2016 were selected and randomly divided into a control group and a research group, with 60 patients in each. All patients were treated with conventional treatments, while the research group were treated with Danhong injection on the basic of the control group. The improvements of clinical symptoms, electrocardiogram and adverse reactions were observed, the levels of IL-6 and IL-17 before and after treatment for 3, 7 d were detected, and the left ventricular ejection fraction (LVEF) and myocardial infarction area in the two groups were compared. The patients were followed-up for 6 months, in which the occurrence of the major adverse cardiovascular events (MACE) were observed. **Results:** The total effective rate was 90.00% in the research group, which was higher than that in the control group (76.67%), the difference was statistically significant ( $P<0.05$ ). The levels of IL-6 were  $(56.38\pm10.75)$  ng/mL and  $(42.52\pm8.14)$  ng/mL in the research group after treatments for 3 and 7 d, which were lower than that in the control group [ $(62.73\pm12.08)$  ng/mL and  $(51.65\pm9.78)$  ng/mL], differences were statistically significant ( $P<0.05$ ). The levels of IL-17 were  $(28.73\pm5.68)$  ng/mL and  $(22.54\pm4.55)$  ng/mL in the research group after treatment for 3 and 7 d, which were lower than that in control group [ $(34.39\pm6.21)$  ng/mL and  $(29.82\pm5.74)$  ng/mL], the difference was statistically significant ( $P<0.05$ ). The LVEF was  $54.72\%\pm5.64\%$  in the research group after treatment, which was higher than that in the control group ( $49.38\%\pm4.57\%$ ), the difference was statistically significant ( $P<0.05$ ). The myocardial infarction area was  $10.64\%\pm4.38\%$  in the research group after treatments for 3 and 7 d, which was lower than that in the control group ( $16.74\%\pm5.49\%$ ), the difference was statistically significant ( $P<0.05$ ). The occurrence rate of MACE was 5.00%, while that in the control group was 16.67%, the difference was statistically significant ( $P<0.05$ ). **Conclusion:** Patients with acute myocardial infarction after PCI in treatments of Danhong injection can reduce the levels of IL-6 and IL-17, improve cardiac function, reduce the myocardial infarction area, and lower the occurrence rate of MACE, which is worthy of clinical use.

**Keywords** Danhong injection; acute myocardial infarction; percutaneous coronary intervention; IL-6; IL-17

急性心肌梗死(acute myocardial infarction, AMI)包括ST抬高型心肌梗死(ST-elevation myocardial infarction, STEMI)和非ST抬高型心肌梗死, 是临幊上常见的危急重症之一, 具有高致残率、高致死率等特点, 严重威胁患者的生命健康。经皮冠状动脉介入治疗(percutaneous coronary intervention, PCI)是目前临幊上治疗STEMI的有效方法, 但术后患者容易出现心肌缺血-再灌注损伤, 从而影响PCI的治疗效果<sup>[1]</sup>。因此, 如何减少PCI术后的再灌注损伤是目前临幊上迫切需要解决的问题。近年来研究<sup>[2]</sup>显示: 炎症反应与PCI术后再灌注损伤密切相关, 而IL-6和IL-17在PCI术后再灌注损伤中发挥重要作用。丹红注射液以丹参、红花为主要成分, 具有活血化瘀、通脉舒络的功效, 现已广泛应用于心脑血管疾病的治疗中, 并取得良好的疗效。研究<sup>[3]</sup>显示: 丹红注射液可有效改善老年急性冠脉综合征患者PCI术后血管内皮功能, 并降低血清IL-6, MMP-9和hs-CRP水平。为

此, 本研究采用丹红注射液治疗PCI术后的STEMI患者, 旨在探讨其对患者血清IL-6和IL-17水平的影响。

## 1 对象与方法

### 1.1 对象

选取2014年6月至2016年1月第四军医大学唐都医院心内科急诊PCI术后的120例STEMI患者作为研究对象, 按随机数字表法分为对照组和研究组, 每组各60例。对照组男36例, 女24例, 年龄 $56\sim78(64.38\pm2.12)$ 岁, 其中 $<6$  h成功对罪犯血管施行PCI者22例,  $6\sim12$  h成功对罪犯血管施行PCI者26例,  $13\sim24$  h成功对罪犯血管施行PCI者12例; 研究组男38例, 女22例, 年龄 $58\sim80(65.13\pm2.38)$ 岁, 其中 $<6$  h成功对罪犯血管施行PCI者23例,  $6\sim12$  h成功对罪犯血管施行PCI者24例,  $13\sim24$  h成功对罪犯血管施行PCI者13例。纳入标准: 1)患者的纳入符

合《急性心肌梗死诊断治疗指南》中STEMI的诊断标准<sup>[4]</sup>，56~80岁，男女不限；2)冠脉造影证实梗死相关动脉残余狭窄<50%，无血管夹层、痉挛；3)造影证实冠状动脉存在前向血流障碍，包括心肌梗死溶栓治疗临床试验(thrombolysis in myocardial infarction，TIMI)血流≤2级或TIMI血流达到3级但TIMI心肌灌注分级(TIMI myocardial perfusion grading，TMPG)≤2级。排除标准：1)合并严重心力衰竭或肝、肾功能不全的患者；2)合并严重感染性疾病、自身免疫性疾病的患者；3)合并凝血功能异常或恶性肿瘤的患者；4)患有精神意识障碍而不能配合治疗的患者；5)对所研究药物过敏的患者等。本研究经第四军医大学唐都医院伦理委员会批准，所有患者均签署知情同意书。两组性别、年龄等一般资料差异无统计学意义( $P>0.05$ ，表1)，两组间具有可比性。

1.2 方法

两组PCI术后均接受常规治疗，包括抗心肌缺血治疗(单硝酸异山梨酯、钙离子通道阻滞剂、 $\beta$ -受体阻滞剂)、抗血小板凝集(肠溶阿司匹林、氯吡格雷)、抗凝治疗(低分子肝素钙)等。而研究组则在对照组治疗的基础上给予丹红注射液(国药准字120026866，济南步长制药有限公司)治疗，即将丹红注射液40 mL溶于5%的葡萄糖溶液250 mL中，静脉滴注，1次/d。两组均连续治疗14 d。

### 1.3 观察指标

观察两组临床症状和体征的改善情况及心电图的恢复情况，评估两组的临床疗效。于治疗前和治疗3, 7 d后，抽取患者清晨空腹静脉血5 mL，不加抗凝剂，室温放置1 h，离心5 min并取上清液。检测两组治疗前血清肌酸激酶(creatine kinase, CK)、肌酸激酶同工酶(creatine kinase isoenzymes, CK-MB)和心肌肌钙蛋白T(cardiac troponin I, cTnT)的水平。采用ELISA法(试剂盒由武汉博士德生物工程有限公司提供，严格按照试剂盒说明书进行操作)检查患者血清IL-6和IL-17的水平。于治疗前后采用彩色多普勒超声心动图检查两组的左室射血分数(left ventricular ejection fractions, LVEF)，并采用心肌核素扫描计算两组治疗前后的心肌梗死面积，所有操作由同一医师执行。随访6个月，观察两组MACE的发生情况，包括心绞痛、心力衰竭、再发性心肌梗死、心源性死亡等。

## 1.4 临床疗效评定标准 [5]

1) 显效：心绞痛基本不发作或发作次数减少 $>80\%$ ，硝酸甘油用量减少 $>80\%$ ，心电图ST段恢复 $\geq 0.1$  mV，抬高的ST段回落 $\geq 50\%$ 或倒置性T变直立；2) 有效：心绞痛次数或硝酸甘油用量减少 $>50\%$ ，心电图ST段恢复 $\geq 0.05$  mV或主要导联T波变浅 $\geq 50\%$ ；3) 无效：未达到上述标准，甚至出现病情加重或死亡。总有效率=(显效+有效)/总病例数×100%。

表1 两组一般资料的比较( $n=60$ )

**Table 1 Comparison of general data between the two groups ( $n=60$ )**

## 1.5 统计学处理

SPSS19.0统计学软件分析数据, 两组计量资料的比较采用t检验, 计数资料的比较采用卡方检验,  $P<0.05$ 为差异有统计学意义。

## 2 结果

### 2.1 两组临床疗效的比较

研究组治疗的总有效率为90.00%, 显著高于对照组的76.67%, 两组间差异有统计学意义( $P<0.05$ , 表2)。

### 2.2 两组治疗前和治疗3, 7 d后血清IL-6和IL-17的水平的比较

研究组治疗3, 7 d后血清IL-6水平分别为( $56.38\pm10.75$ )和( $42.52\pm8.14$ ) ng/mL, 均显著低于对照组的( $62.73\pm12.08$ )和( $51.65\pm9.78$ ) ng/mL, 两组间差异有统计学意义( $P<0.05$ ); 研究组治疗3, 7 d后血清IL-17水平分别为( $28.73\pm5.68$ )和( $22.54\pm4.55$ ) ng/mL, 均显著低于

对照组的( $34.39\pm6.21$ )和( $29.82\pm5.74$ ) ng/mL, 两组间差异有统计学意义( $P<0.05$ , 表3)。

### 2.3 两组治疗前后LVEF和心肌梗死面积的比较

研究组治疗后的LVEF为 $54.72\%\pm5.64\%$ , 显著高于对照组的 $49.38\%\pm4.57\%$ , 两组间差异有统计学意义( $P<0.05$ ); 研究组治疗后的心肌梗死面积为 $10.64\%\pm4.38\%$ , 明显低于对照组的 $16.74\%\pm5.49\%$ , 两组间差异有统计学意义( $P<0.05$ , 表4)。

### 2.4 两组MACE发生情况的比较

研究组的MACE发生率为5.00%, 显著低于对照组的16.67%, 两组间有统计学差异( $P<0.05$ , 表5)。

### 2.5 两组不良反应发生情况的比较

对照组出现轻度消化道出血2例; 而研究组则出现轻度消化道出血1例, 皮疹1例。两组患者经对症治疗或停药后, 症状均已缓解, 不影响治疗, 无1例患者因不良反应退出研究。

表2 两组临床疗效的比较(n=60)

Table 2 Comparison of clinical curative effect between the two groups (n=60)

| 组别  | 显效/[例(%)]  | 有效/[例(%)]  | 无效/[例(%)]  | 总有效率/% |
|-----|------------|------------|------------|--------|
| 研究组 | 21 (35.00) | 33 (55.00) | 6 (10.00)  | 90.00  |
| 对照组 | 16 (26.67) | 30 (50.00) | 14 (23.33) | 76.67  |

$\chi^2=3.8400$ ,  $P<0.05$ 。

表3 两组治疗前和治疗3, 7 d后血清IL-6和IL-17的水平的比较(n=60,  $\bar{x}\pm s$ )

Table 3 Comparison of serum IL-6 and IL-17 between the two groups before and after treatment for 3 or 7 d (n=60,  $\bar{x}\pm s$ )

| 组别  | IL-6/(ng·mL <sup>-1</sup> )  |               |              | F       | P     |
|-----|------------------------------|---------------|--------------|---------|-------|
|     | 治疗前                          | 治疗3d          | 治疗7d         |         |       |
| 研究组 | 44.58 ± 8.73                 | 56.38 ± 10.75 | 42.52 ± 8.14 | 22.7812 | <0.05 |
| 对照组 | 45.24 ± 9.25                 | 62.73 ± 12.08 | 51.65 ± 9.78 | 14.6973 | <0.05 |
| t   | 0.4019                       | 3.0417        | 5.5579       |         |       |
| P   | >0.05                        | <0.05         | <0.05        |         |       |
| 组别  | IL-17/(ng·mL <sup>-1</sup> ) |               |              | F       | P     |
|     | 治疗前                          | 治疗3d          | 治疗7d         |         |       |
| 研究组 | 26.14 ± 5.23                 | 28.73 ± 5.68  | 22.54 ± 4.55 | 12.7456 | <0.05 |
| 对照组 | 25.49 ± 4.98                 | 34.39 ± 6.21  | 29.82 ± 5.74 | 8.4679  | <0.05 |
| t   | 0.6972                       | 5.2095        | 7.6988       |         |       |
| P   | >0.05                        | <0.05         | <0.05        |         |       |

**表4 两组治疗前后左室射血分数和心肌梗死面积的比较( $n=60$ ,  $\bar{x} \pm s$ )**

**Table 4 Comparison of left ventricular ejection fraction and the myocardial infarction area in two groups before and after treatment ( $n=60$ ,  $\bar{x} \pm s$ )**

| 组别  | LVEF/%       |              | 心肌梗死面积/%     |              |
|-----|--------------|--------------|--------------|--------------|
|     | 治疗前          | 治疗后          | 治疗前          | 治疗后          |
| 研究组 | 42.24 ± 6.23 | 54.72 ± 5.64 | 22.42 ± 8.67 | 10.64 ± 4.38 |
| 对照组 | 43.58 ± 5.48 | 49.38 ± 4.57 | 21.08 ± 8.92 | 16.74 ± 5.49 |
| t   | 1.2510       | 5.6982       | 0.8344       | 6.7278       |
| P   | >0.05        | <0.05        | >0.05        | <0.05        |

**表5 两组MACE发生率的比较( $n=60$ )**

**Table 5 Comparison of MACE incidence between the two groups ( $n=60$ )**

| 组别  | 心绞痛/[例(%)] | 心力衰竭/[例(%)] | 再发性心肌梗死/[例(%)] | 心源性死亡/[例(%)] | MACE发生率/[例(%)] |
|-----|------------|-------------|----------------|--------------|----------------|
| 研究组 | 2 (6.67)   | 1 (1.67)    | 0 (0.00)       | 0 (0.00)     | 3 (5.00)       |
| 对照组 | 7 (11.67)  | 2 (6.67)    | 1 (1.67)       | 0 (0.00)     | 10 (16.67)     |

$\chi^2=4.2272$ ,  $P<0.05$ .

### 3 讨论

近年来，随着我国社会人口老龄化的加剧，AMI的发病率呈逐年上升的趋势，已引起人们的普遍关注。PCI术治疗是目前临幊上治疗STEMI的有效方法，其可通过解除冠状动脉狭窄、重建血管，恢复心肌灌注，从而达到治疗的目的<sup>[6]</sup>。相关文献[7]报道：PCI术后患者恢复缺血心肌血供的同时，可加重心肌细胞的损伤，即造成患者的心肌缺血-再灌注损伤，从而影响PCI的治疗效果。因此，如何减少PCI术后的再灌注损伤是目前临幊上迫切需要解决的问题<sup>[8]</sup>。

有研究<sup>[9]</sup>显示：炎症反应是PCI术后心肌缺血-再灌注损伤的主要病理机制，通过抑制PCI术后的炎症反应，有助于减轻心肌缺血-再灌注损伤。IL-17是一种促炎症因子，与慢性炎症、动脉粥样硬化和血栓形成密切相关<sup>[10-11]</sup>。而IL-6作为体内一种强致炎因子，亦在AMI的发生发展中发挥着重要的作用<sup>[12]</sup>。动物试验<sup>[13-14]</sup>结果显示：IL-6和IL-17均参与大鼠的心肌缺血-再灌注损伤过程。郑炜华等<sup>[15]</sup>研究结果亦显示：PCI术后STEMI患者血清IL-17和IL-6水平显著升高。

对丹红注射液结合缺血后处理对小型猪心肌缺血-再灌注损伤的研究<sup>[16]</sup>结果显示，丹红注射液

结合缺血后处理组心肌梗死面积最小，而与对照组比较，丹红注射液结合缺血后处理心肌纤维排列更有序，炎性细胞的浸润减少和线粒体的完整性更高。有研究<sup>[17]</sup>亦证实：丹红注射液对冠心病心绞痛的治疗有良好的效果。但目前有关丹红注射液用于PCI术后患者治疗的研究尚少，为此，本研究采用丹红注射液治疗PCI术后的STEMI患者，并进一步探讨其对患者血清IL-6和IL-17水平的影响。本研究结果提示：丹红注射液可有效改善心肌组织再灌注损伤，减少心肌重构，改善心功能，与文献<sup>[18]</sup>报道结果相符。丹红注射液的有效成分主要包括丹参酮、红花黄色素等，其中丹参酮具有抗动脉粥样硬化的作用，可抑制血小板的凝集和血栓的形成，从而降低因血栓脱落等原因导致心肌缺血坏死的风险。此外，丹参酮亦可通过抑制白细胞黏附和肥大细胞脱颗粒，清除缺血心肌氧自由基，提高心肌组织抗氧化能力，从而发挥减轻再灌注损伤、保护血管内皮功能的作用，改善心功能<sup>[19]</sup>。红花黄色素具有抗缺氧和抑制血小板凝集的作用，亦对心肌细胞具有保护的作用。本研究结果亦提示：丹红注射液发挥抗炎作用及其对患者缺血再灌注损伤的保护作用可能与下调IL-6和IL-17的表达水平有关。丹红注射液辅助急诊PCI治疗STEMI，在稳定动脉粥样硬化

斑块、抑制炎症反应等方面发挥着潜在的防治优势, 为临床治疗提供了理论支持。而有关丹红注射液是如何影响IL-6和IL-17表达而发挥抗炎作用的机制则有待进一步更大样本量的研究。

综上所述, 丹红注射液可有效降低PCI术后STEMI患者血清L-6和IL-17的水平, 改善患者心功能, 缩小心肌梗死面积, 降低MACE的发生率, 安全有效, 值得应用于临床。

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