

# 阿瑞匹坦联合托烷司琼预防顺铂化疗引起呕吐的临床观察

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**摘要** 目的:观察阿瑞匹坦联合托烷司琼方案预防顺铂化疗引起呕吐的疗效及不良反应。方法:采用随机、自身交叉对照的方法,将60例接受两周期含顺铂联合化疗的患者,随机分为AB、BA组。AB组第1周期应用阿瑞匹坦联合托烷司琼,第2周期应用托烷司琼;BA组第1周期应用托烷司琼,第2周期应用阿瑞匹坦联合托烷司琼。结果:可评价疗效的59例患者中,阿瑞匹坦联合托烷司琼方案和托烷司琼方案对急性呕吐的完全缓解率分别为74.6%和57.6%,有效控制率分别为91.5%和81.4% ( $Z=-2.017, P=0.044$ );对延迟性呕吐的完全缓解率分别为69.5%和42.4%,有效控制率分别为86.4%和71.2% ( $Z=-3.112, P=0.002$ )。两种方案的主要不良反应为呃逆、便秘、头痛、头晕、口干等,不良反应发生率比较差异无统计学意义 ( $P>0.05$ )。结论:阿瑞匹坦联合托烷司琼方案对顺铂化疗引起急性呕吐与延迟性呕吐均有很好的疗效,不良反应可以耐受。

**关键词** 阿瑞匹坦;托烷司琼;顺铂;化疗;呕吐

## Clinical Observation of Aprepitant Combined with Tropisetron in the Prevention of Vomiting Induced by Cisplatin Chemotherapy

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**ABSTRACT** OBJECTIVE: To observe clinical efficacy and ADR of aprepitant combined with tropisetron in the prevention of vomiting induced by cisplatin chemotherapy. METHODS: Randomized self-cross controlled method was applied. All 60 patients who received two courses of cisplatin based chemotherapy were randomized into group AB and BA. Group AB received aprepitant combined with tropisetron in the first cycle while tropisetron alone in the second cycle. Group BA was given tropisetron alone in the first cycle while aprepitant combined with tropisetron in the second cycle. RESULTS: Among 59 patients who achieved the assessment of clinical response, the complete response rates of acute vomiting by aprepitant combined with tropisetron vs. tropisetron were 74.6% vs. 57.6%; the control rate were 91.5% vs. 81.4%, respectively ( $Z=-2.017, P=0.044$ ); the complete response rate of delayed vomiting was 69.5% vs. 42.4%, and the control rates were 86.4% vs. 71.2% ( $Z=-3.112, P=0.002$ ). The most common ADR in both regimens were hiccups, constipation, headache, dizziness, mouth dry, etc. There was no statistical significance in the incidence of ADR ( $P>0.05$ ). CONCLUSIONS: The aprepitant combined with tropisetron regimen is effective for acute and delayed vomiting induced by cisplatin chemotherapy, with tolerable toxicity profile.

**KEYWORDS** Aprepitant; Tropisetron; Cisplatin; Chemotherapy; Vomiting

治疗组中有8例出现不同程度局部发红、烧灼感,经用保护剂对症治疗及解释,患者均完成疗程。研究中,笔者发现对于皮损苔藓化明显,增生显著者基本无局部发红及烧灼感,疗效较好,这可能与此类皮损增生明显、炎症反应较轻而卡泊三醇有明显抗角化增生作用同时与氟芬那酸丁酯软膏抗炎、止痒作用协同,从而达到较好的临床效果。特别是对于一些不愿长期使用糖皮质激素或皮疹反复发作的头部患者是一种较好的替代治疗方案。

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化疗引起的恶心呕吐(CINV)常常造成患者拒绝治疗或恐惧治疗,从而延误治疗时机。目前临床上用于控制CINV的药物主要有5-HT<sub>3</sub>受体拮抗药和神经激肽(NK-1)受体拮抗药。5-HT<sub>3</sub>受体拮抗药对急性恶心呕吐有良好的效果,但对于迟发性呕吐效果欠佳;而NK-1受体拮抗药对于迟发性呕吐的作用优于5-HT<sub>3</sub>受体拮抗药。两者联合应用能提高治疗急性和延迟性CINV的疗效。为评价NK-1受体拮抗药阿瑞匹坦联合5-HT<sub>3</sub>受体拮抗药托烷司琼预防顺铂化疗引起的呕吐的疗效及安全性,笔者采用随机、自身交叉对照的方法对60例接受顺铂化疗的患者进行临床观察,现报道如下。

## 1 资料与方法

### 1.1 研究对象

入组我科2013年12月—2014年2月经病理学或细胞学诊断的恶性肿瘤患者60例,无颅内高压、胃肠梗阻或其他原因引起的顽固性呕吐者,无消化性溃疡病史。化疗前24 h内呕吐或者用过止吐药者不予入组。计划接受2个周期以上顺铂化疗。所有患者按美国东部肿瘤协作组(ECOG)体力状态评分≤2分,预计生存期3个月以上,血常规、肝肾功能、心电图在正常范围。入组患者均签署知情同意书。该治疗方案经医院医学伦理委员会批准通过。

60例患者入组,1例患者因化疗1周期后肿瘤进展未能完成2个周期,视为剔除病例。其中男性32例,女27例;年龄25~70岁;非小细胞肺癌24例,鼻咽癌16例,胃癌11例,食管癌8例。实际完成观察为AB组33例、BA组26例。两组患者的年龄、ECOG评分、性别、肿瘤类型、化疗方案等方面,差异无统计学意义,见表1。

表1 两组患者临床特征比较

Tab 1 Comparison of clinical characteristics of patients between 2 groups

项目	AB组	BA组	检验值	P
年龄,岁	45.1±8.4	43.1±9.5	<i>t</i> =0.691	0.503
ECOG,例				
0	22	18	<i>Z</i> =-0.223	0.823
1	8	6		
2	3	2		
性别,例				
男	18	14	$\chi^2$ =0.603	0.438
女	15	12		
肿瘤类型,例				
肺癌	14	10	<i>Z</i> =-0.177	0.860
鼻咽癌	8	8		
胃癌	7	4		
食管癌	4	4		
化疗方案,例				
吉西他滨+顺铂	10	8	<i>Z</i> =-0.031	0.975
紫杉醇+顺铂	8	6		
多西他赛+顺铂	6	4		
氟尿嘧啶+顺铂	7	6		
其他	2	2		

### 1.2 治疗方法

1.2.1 化疗方案。不同恶性肿瘤所选用的化疗方案不同,但都采用顺铂化疗(25 mg/m<sup>2</sup>,第1~3天,21 d为1个周期)。其他各种化疗药均按标准剂量给予。同一患者2个周期化疗方案及实施方法一致。

1.2.2 分组。使用随机数字表法的随机方式,自身交叉对照,

将入组的患者分为AB组与BA组。AB组第1周期应用阿瑞匹坦联合托烷司琼(A方案:阿瑞匹坦125 mg口服第1天,80 mg第2~3天;托烷司琼5 mg+生理盐水100 ml化疗前30 min静脉滴注,qd,第1~5天);第2周期单用托烷司琼(B方案:托烷司琼5 mg+生理盐水100 ml化疗前30 min静脉滴注,qd,第1~5天)。BA组与AB组用药顺序相反,即第1周期(B方案),第2周期(A方案)。

1.2.3 安全性观察。化疗期间动态监测血常规每周2次,肝肾功能电解质每2周1次。记录化疗开始第1~5天患者呕吐的次数、是否使用挽救治疗等。如肿瘤进展或者出现不能耐受的治疗毒副反应时研究终止。观察患者呃逆、便秘、头晕、头痛、过敏、口干及其他不良反应。

### 1.3 疗效评价

根据2003年美国国家癌症研究所化疗药品不良反应判定标准(NCI-CTCAE V 3.0)<sup>[1]</sup>进行观察。止吐疗效分为完全缓解(CR):无呕吐;部分缓解(PR):轻微呕吐1~2次/d;轻度缓解(MR):呕吐3~5次/d;无效(F):呕吐>6次/d。记录化疗开始第1~5天患者呕吐的次数、是否使用挽救治疗等。有效控制率以CR+PR计算。

### 1.4 统计学分析

采用SPSS 20.0统计软件进行分析,计量资料组间比较采用*t*检验,计数资料组间比较采用 $\chi^2$ 检验,等级资料组间比较采用秩和检验。*P*<0.05为差异有统计学意义。

## 2 结果

### 2.1 两种止吐方案对急性呕吐的疗效比较

化疗24 h内,阿瑞匹坦联合托烷司琼方案(A方案)和托烷司琼方案(B方案)止吐的CR率分别为74.6%、57.6%,有效控制率分别为91.5%、81.4% (*Z*=-2.017, *P*=0.044),见表2。

表2 两种止吐方案对急性呕吐的疗效比较

Tab 2 Comparison of therapeutic efficacy for acute vomiting between two antiemetic regimens

止吐方案	止吐疗效,例				CR率, %	有效控 制率, %	<i>Z</i>	<i>P</i>
	CR	PR	MR	F				
A方案	44	10	3	2	74.6	91.5	-2.017	0.044
B方案	34	14	7	4	57.6	81.4		

### 2.2 两种止吐方案对延迟性呕吐的疗效比较

化疗后24~120 h内,A方案和B方案止吐的CR率分别为69.5%、42.4%,有效控制率分别为86.4%、71.2% (*Z*=-3.112, *P*=0.002),见表3。

表3 两种止吐方案对延迟性呕吐的疗效比较

Tab 3 Comparison of therapeutic efficacy for delayed vomiting between two antiemetic regimens

止吐方案	止吐疗效,例				CR率, %	有效控 制率, %	<i>Z</i>	<i>P</i>
	CR	PR	MR	F				
A方案	41	10	7	1	69.5	86.4	-3.112	0.002
B方案	25	17	7	10	42.4	71.2		

### 2.3 两种止吐方案的不良反应比较

两种止吐方案主要不良反应包括呃逆、便秘、疲倦、头痛、头晕、心悸、口干、焦虑等。其中A方案的I~IV度便秘发生率为25.4%(15/59),B方案的I~IV度便秘发生率为20.3%(12/59),两种方案比较,便秘发生率差异无统计学意义。其余不良反应发生率比较,两组差异均无统计学意义(*P*>0.05),见表4。

表4 两种止吐方案不良反应比较(例)

Tab 4 Comparison of ADR between two antiemetic regimens(case)

不良反应	A方案					B方案					Z	P
	0	I	II	III	IV	0	I	II	III	IV		
呃逆	53	5	1	0	0	56	2	1	0	0	-1.018	0.309
疲倦	43	9	7	0	0	45	7	7	0	0	-0.367	0.714
头痛	53	4	2	0	0	51	5	3	0	0	-0.576	0.565
头晕	54	4	1	0	0	55	3	1	0	0	-0.399	0.734
便秘	44	12	3	0	0	47	11	1	0	0	-0.729	0.466
心悸	58	1	0	0	0	58	1	0	0	0	-0.000	1.000
口干	47	11	1	0	0	49	9	1	0	0	-0.462	0.644
焦虑	55	2	2	0	0	56	2	1	0	0	-0.401	0.688
失眠	52	5	2	0	0	54	3	2	0	0	-0.585	0.558
厌食	47	10	2	0	0	46	9	4	0	0	-0.306	0.759
皮疹	57	2	0	0	0	58	1	0	0	0	-1.582	0.560

### 3 讨论

CINV可能会导致患者出现脱水、电解质紊乱、营养不良,严重者可能因消化道黏膜损伤而发生出血、感染甚至死亡。如何防治CINV已是临床肿瘤科医师面临的重要课题之一。CINV机制目前尚未完全清楚,多认为与中枢及外周神经系统有关,与多巴胺、组胺、5-HT<sub>3</sub>、P物质等有关<sup>[2]</sup>。P物质属于速激肽家族,速激肽受体共有3种亚型,即NK-1、NK-2、NK-3受体。P物质兴奋NK-1受体引起呕吐。NK-1受体拮抗药与NK-1受体结合,阻滞P物质的作用<sup>[3]</sup>。阿瑞匹坦作为第1个NK-1受体拮抗药,于2003年研发上市,标志着新一代止吐药进入临床应用。Chapell和Paul分别研究发现,在应用高致吐性化疗方案中,5-HT<sub>3</sub>受体拮抗药联合应用阿瑞匹坦可以改善CINV<sup>[4-5]</sup>。

既往的大量研究表明,5-HT<sub>3</sub>受体拮抗药对急性恶心呕吐有良好的效果<sup>[6]</sup>。作为5-HT<sub>3</sub>受体拮抗药的托烷司琼具有双重阻滞作用,既可以阻滞呕吐中枢外周神经元的突触前5-HT<sub>3</sub>受体兴奋,又能直接作用于中枢神经系统5-HT<sub>3</sub>传递<sup>[7]</sup>。徐舒等<sup>[8]</sup>研究发现,托烷司琼预防化疗所致呕吐取得较好疗效,对急性呕吐CR率为61.9%。Jang G等<sup>[9]</sup>研究发现5-HT<sub>3</sub>受体拮抗药与地塞米松联合阿瑞匹坦对急性呕吐CR率达94.9%,提示联合阿瑞匹坦改善了对急性呕吐的疗效。其他文献也得到类似的结果<sup>[10]</sup>。本研究中单用托烷司琼,对急性呕吐的CR率为57.6%,阿瑞匹坦联合托烷司琼对急性呕吐的CR率为74.6%,两个方案对急性呕吐疗效比较差异有统计学意义。

对于迟发性呕吐,5-HT<sub>3</sub>受体拮抗药疗效不佳,目前具体原因尚不清楚。文献报道5-HT<sub>3</sub>受体拮抗药对于迟发性呕吐的有效率为55.8%~90.4%<sup>[11-12]</sup>。阿瑞匹坦的Ⅲ期临床研究表明,以高剂量顺铂为基础的化疗,口服阿瑞匹坦加昂丹司琼和地塞米松对迟发性呕吐的疗效优于昂丹司琼和地塞米松,且不良反应少。Hu Z等<sup>[13]</sup>等研究发现在5-HT<sub>3</sub>受体拮抗药、地塞米松基础上联合用阿瑞匹坦对控制迟发性呕吐的CR率为74.0%。本研究中阿瑞匹坦联合托烷司琼对迟发性呕吐的CR率为69.5%,而单用托烷司琼的CR率为42.4%,提示加用阿瑞匹坦可以改善顺铂所致迟发性呕吐。

本文对两种方案进行了不良反应分析,两组均出现了呃逆、便秘、头痛、头晕、口干等,两种方案不良反应比较差异无统计学意义,与既往文献报道<sup>[14]</sup>相似。其中阿瑞匹坦联合托烷司琼治疗方案(A方案)的便秘发生率为25.4%(15/59),单用托烷司琼治疗方案(B方案)的便秘发生率为20.3%(12/59),两种方案比较,便秘发生率差异无统计学意义( $P>0.05$ )。两种方案其

余不良反应比较差异无统计学意义,提示加用阿瑞匹坦没有增加不良反应。

本研究主要是评估阿瑞匹坦联合托烷司琼预防顺铂化疗引起呕吐的有效性和安全性。与单用托烷司琼方案相比,本研究中阿瑞匹坦联合托烷司琼方案均改善了急性及延迟性呕吐的CR率与有效控制率,且不良反应少、安全性高、应用方便,更适合于接受高致吐性化疗方案患者。因本研究病例数相对较少,还有待进一步累积样本研究。

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# 瑞替普酶联合择期PCI治疗急性ST段抬高型心肌梗死的疗效观察

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**摘要** 目的:观察瑞替普酶与尿激酶静脉溶栓联合择期经皮冠状动脉介入治疗(PCI)对急性心肌梗死的疗效及安全性。方法:按用药情况将72例急性ST段抬高型急性心肌梗死患者分为尿激酶组47例与瑞替普酶组25例。入选患者明确诊断后常规给予硫酸氢氯吡格雷、肠溶阿司匹林。瑞替普酶组静脉溶栓采用瑞替普酶治疗,18 mg(10 MU)分2次静脉注射,每次缓慢静脉注射2 min以上,两次间隔30 min。尿激酶组采用尿激酶150万U静脉滴注,用药后12 h用低分子肝素5 000 u,q12h(连用,5~7 d)。两组患者均于溶栓后3~24 h内进行血管造影,必要时PCI治疗,其他治疗相同。观察两组血管再通率和恶性心律失常、心力衰竭、出血、死亡发生率,以及冠脉造影及PCI后血管开通率和支架安置率。结果:瑞替普酶组与尿激酶组2 h内胸痛消失或缓解者分别占80.00%、61.70% ( $P<0.05$ ),溶栓后2 h内ST回落 $>50\%$ 的患者分别占92.00%、65.96% ( $P<0.05$ ),酶峰[心肌酶肌酸激酶(CK)及肌酸激酶同工酶(CK-MB)峰值]提前者分别占92.00%、53.19% ( $P<0.05$ ),梗死相关动脉(IRA)再通率分别为92.00%、68.09% ( $P<0.05$ ),IRA完全开通率分别为52.00%、31.91% ( $P<0.05$ )。瑞替普酶组的恶性心律失常、心力衰竭等并发症发生率及死亡率分别为36.00%、4.00%、4.00%、0,均低于尿激酶组(分别为51.06%、12.77%、10.64%、6.38%),差异均有统计学意义( $P<0.05$ );瑞替普酶组支架安置率(36.00%)明显低于尿激酶组(53.19%) ( $P<0.05$ )。结论:瑞替普酶联合择期PCI治疗急性心肌梗死具有血管开通率高,时间短,恶性心律失常、心力衰竭、出血等并发症少,死亡率低的优点。

**关键词** 急性心肌梗死;瑞替普酶;尿激酶;经皮冠状动脉介入治疗

## Efficacy Observation of Reteplase Combined with Selective PCI Treatment for Acute ST-segment Elevation Myocardial Infarction

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**ABSTRACT** OBJECTIVE: To observe therapeutic efficacy and safety of intravenous thrombolysis of reteplase and urokinase combined with selective PCI treatment for acute myocardial infarction (AMI). METHODS: 72 cases of acute ST-segment elevation acute myocardial infarction were divided into urokinase group (47 cases) and reteplase group (25 cases). After diagnosed, the enrolled patients were routinely given clopidogrel bisulfate and enteric coated aspirin. Reteplase group received intravenous thrombolysis therapy of reteplase, 18 mg (10 MU) in total for twice intravenous injection, over 2 min each time, at 30 min intervals. Urokinase group received 1.5 million U urokinase intravenously, and was given macromolecules low molecular weight heparin 5 000 u,q12h (5-7 d) 12 h later. Angiography was carried out in 2 groups within 3 to 24 h after thrombolysis, and they received PCI if necessary. Other treatments of them were the same to each other. The recanalization rate and the incidence of malignant arrhythmias, the incidence of heart failure and bleeding, mortality, coronary angiography and vessel patency rate after PCI and stent placement rates were observed in 2 groups. RESULTS: The chest pain relief or disappearance of reteplase group and urokinase group within 2 h accounted for 80.00% and 61.70% ( $P<0.05$ ). The patients with ST-segment recovery  $>50\%$  within 2 h after thrombolysis accounted for 92.00% and 65.96% ( $P<0.05$ ); the patients with premature enzymes peak (CK and CK-MB peak) accounted for 92.00% and 53.19% ( $P<0.05$ ). The recanalization rates of infarct-related artery (IRA) were 92.00% and 68.09% ( $P<0.05$ ), and IRA patency rate were 52.00% and 31.91%, respectively ( $P<0.05$ ). The incidence of malignant arrhythmias, heart failure, ADR and mortality were 36.00%, 4.00%, 4.00% and 0 in reteplase group, which were all lower than urine kinase group (51.06%, 12.77%, 10.64% and 6.38%); there was statistical significance ( $P<0.05$ ). The stent placement rate of reteplase group (36.00%) was significantly lower than that of urokinase group (53.19%) ( $P<0.05$ ). CONCLUSIONS: Reteplase combined elective PCI treatment for acute myocardial infarction is characterized with the advantage of high patency rate, time-saving, less complications as malignant arrhythmias, heart failure and bleeding, and low mortality.

**KEYWORDS** Acute myocardial infarction; Reteplase; Urokinase; Percutaneous coronary intervention

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