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昂丹司琼联合泮托拉唑对宫颈癌同步放化疗所致恶心呕吐的临床疗效 *

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摘要 目的:研究昂丹司琼联合泮托拉唑对宫颈癌同步放化疗所致恶心呕吐的临床疗效。**方法:**选择 2018 年 1 月~2020 年 1 月我院收治的 79 例宫颈癌患者,均采取同步化疗,将其随机分为两组。对照组在当天化疗前 30 min 和随后的 6 d 连续静脉注射昂丹司琼,每次 8 mg,1 次/d;同时给予地塞米松磷酸钠注射液 10 mg,1 次/d。观察组在昂丹司琼的基础上静脉注射泮托拉唑,每次 40 mg,1 次/d,给药的时间与昂丹司琼相同。比较两组宫颈癌患者恶心呕吐的完全缓解率、癌因性疲乏评分和不良反应的发生情况。**结果:**两组化疗第 1、2 d 恶心呕吐的完全缓解率比较差异无明显统计学意义($P>0.05$),观察组化疗第 3、4、5、6 d 恶心呕吐的完全缓解率分别为 76.92 %、79.49 %、87.18 %、87.18 %,均明显高于对照组($P<0.05$);观察组的癌因性疲乏评分为(45.39±7.29)分,明显低于对照组的(67.24±8.36)分($P<0.05$);两组的乏力嗜睡、便秘、椎体外系反应、失眠/不安、腹泻、轻度头痛的发生率比较无明显统计学差异($P>0.05$)。**结论:**昂丹司琼联合泮托拉唑对宫颈癌同步放化疗所致恶心呕吐的疗效显著优于单用昂丹司琼治疗,并能明显减轻癌因性疲乏,且安全性高。

关键词:昂丹司琼;泮托拉唑;宫颈癌;同步放化疗;恶心呕吐

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Effect of Ondansetron Combined with Pantoprazole on the Nausea and Vomiting in Cervical Cancer Caused by Concurrent Chemoradiotherapy*

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ABSTRACT Objective: To study the clinical efficacy of ondansetron combined with pantoprazole on nausea and vomiting caused by concurrent chemoradiotherapy of cervical cancer. **Methods:** 79 cases of patients with cervical cancer who were treated in our hospital from January 2018 to January 2020 were selected for concurrent chemotherapy, and they were randomly divided into two groups. The control group was given intravenous injection of ondansetron, 8 mg each time, once per day at 30 minutes before chemotherapy and the following 6 days. At the same time, dexamethasone sodium phosphate injection 10 mg was given once daily. In the observation group, intravenous pantoprazole was given on the basis of ondansetron, 40 mg each time, once per day, and the administration time was the same as ondansetron. The complete remission rate of nausea and vomiting, cancer-related fatigue score and the incidence of adverse reactions between the two groups. **Results:** There was no significant difference in the complete remission rate of nausea and vomiting between the two groups on the first, second day of chemotherapy ($P>0.05$). The complete remission rate of nausea and vomiting on the 3rd, 4th, 5th and 6th day of chemotherapy in the observation group were 76.92 %, 79.49 %, 87.18 %, 87.18 %, respectively, all significantly higher than those in the control group ($P<0.05$). The score of cancer-related fatigue in the observation group was (45.39±7.29), which was significantly lower than that in the control group (67.24±8.36, $P<0.05$). There was no significant difference in the incidence of asthenia, sleepiness, constipation, extrvertebral reaction, insomnia / restlessness, diarrhea and mild headache between the two groups ($P>0.05$). **Conclusion:** Ondansetron combined with pantoprazole not only had a significant effect on nausea and vomiting caused by concurrent chemoradiotherapy of cervical cancer, but also could significantly reduce cancer-related fatigue with high safety.

Key words: Ondansetron; Pantoprazole; Cervical Cancer; Concurrent Chemoradiotherapy; Nausea And Vomiting

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前言

宫颈癌的临床发病率高居所有女性生殖道恶性肿瘤中的首位。除了人乳头状瘤病毒之外,多种危险因素在宫颈癌的发生和发展中发挥共同的作用,如多产、早婚、过早性生活、性生活紊乱等^[1-4]。很多宫颈癌患者到医院就诊时已经处在了疾病的中晚期,失去了手术治疗的机会,使得放化疗成为主要的疗法,但放化疗会引起患者恶心呕吐,不利于化疗的顺利进行,进而影响患者的生存期^[5,6]。如何减轻宫颈癌患者放化疗所致的恶心和呕吐反应,是亟待解决的一个重要问题。

目前,临幊上常常使用的止吐剂为昂丹司琼,虽然其效果优于传统的胃复安,但仍有部分患者的胃肠道反应无法得到有效的控制^[7]。泮托拉唑可以特异性地作用于患者胃黏膜壁细胞内的分泌小管,不可逆地与微管内的质子泵-ATP酶的巯基结合,产生明显的抗酸效果^[8]。近年来,基于泮托拉唑强有力的高度抑酸作用能改善各种消化道疾病不适等,国人开始尝试将泮托拉唑用于化疗所致胃肠道反应的防治^[9],但其疗效和安全性尚无定论。因此,本研究将昂丹司琼和泮托拉唑联用,探讨了其对宫颈癌同步放化疗所致恶心呕吐的疗效。

1 资料与方法

1.1 一般资料

选择2018年1月~2020年1月我院收治的79例宫颈癌患者,样本量计算方法采用预实验法。纳入标准:①经病理学检查证实,无胃肠道转移、脑转移、肝转移等,且均行同步放化疗;②无合并严重的慢性疾病;③预计生存期超过3个月,KPS评分≥70分;④肝肾功能、骨髓功能以及心肺功能正常;⑤知情同意。排除标准:①有颅内压升高的患者;②化疗前有胃肠功能异常者,有腹胀、便秘和恶心等不适症状的患者;③合并脑部肿瘤、肝、肾功能异常和脑血管疾病的患者;④消化道梗阻或者由于其他原因导致的顽固性呕吐患者。

79例患者年龄34~65岁,平均年龄(51.83±4.21)岁,Ⅱb期27例,Ⅲa期19例,Ⅲb期23例,Ⅳ期10例。用抽签法将患者随机分为两组。观察组39例,年龄34~65岁,平均(51.34±4.39)岁;Ⅱb期13例,Ⅲa期9例,Ⅲb期12例,Ⅳ期5例。对照组40例,年龄34~65岁,平均(52.27±5.14)岁;Ⅱb期14例,Ⅲa期10例,Ⅲb期11例,Ⅳ期5例。两组的基线资料比较差异均无统计学意义($P>0.05$),具有可比性。

1.2 治疗方法

两组均采取以下同步化疗方案:第1d,静脉滴注紫杉醇135 mg/m²,维持3 h;第1d,静脉滴注顺铂75 mg/m²,维持8 h。患者都以21 d作为一个疗程,共两个疗程。对照组:在当天化疗前30 min 和随后的6 d连续静脉注射昂丹司琼(福安药业集团宁波天衡制药有限公司,国药准字H10960149,规格4 mg/支),每次8 mg,1次/d;同时给予地塞米松磷酸钠注射液(天津金耀集团湖北天药药业股份有限公司,国药准字H42020020,规格1 mL:2 mg/支)10 mg,1次/d。观察组:在昂丹司琼的基础上,静脉注射泮托拉唑(瑞阳制药有限公司,国药准字H20065823,规格40 mg/支),每次40 mg,1次/d。给药时间与昂丹司琼相同。两组无病例脱落,均完成相应的治疗和检查。

1.3 观察指标

疗效根据WHO评价标准^[10]:0度表示患者无恶心并且无呕吐;I度表示患者出现轻微的恶心,24 h内的呕吐次数为1~2次;II度表示患者出现明显的恶心,24 h内的呕吐次数为3~5次,对进食造成影响;III度表示患者出现比较严重的恶心,24 h的内呕吐次数为6~8次,严重影响正常生活和进食;IV度表示患者出现严重的恶心,24 h内的呕吐次数>9次,无法进食而需要卧床。完全缓解率=0级例数/该组总例数。

化疗结束后,采取修订的Piper疲乏量表^[11]评估宫癌患者的癌因性疲乏情况。其中,0分:表示宫颈癌患者无疲乏,1~3分:表示宫颈癌患者轻度疲乏,4~6分:表示宫颈癌患者中度疲乏,7分以上:表示宫颈癌患者重度疲乏。

记录两组乏力嗜睡、便秘、椎体外系反应、失眠/不安、腹泻、轻度头痛的发生情况。

1.4 统计学分析

采用SPSS 20.0进行数据分析,计量资料用 $(\bar{x} \pm s)$ 表示,组间对比用t检验,计数资料用%表示,组间对比行 χ^2 检验,以 $P<0.05$ 为差异有统计学意义。

2 结果

2.1 两组恶心呕吐的疗效对比

两组化疗第1、2 d恶心呕吐的完全缓解率差异无统计学意义无明显差异($P>0.05$),观察组化疗第3、4、5、6 d恶心呕吐的完全缓解率分别为76.92%、79.49%、87.18%、87.18%,均明显高于对照组($P<0.05$),见表1。

2.2 两组癌因性疲乏评分的比较

化疗后,观察组的癌因性疲乏评分为(45.39±7.29)分,明显低于对照组[(67.24±8.36)分]($P<0.05$)。

2.3 两组不良反应发生情况的比较

两组的乏力嗜睡、便秘、椎体外系反应、失眠/不安、腹泻、轻度头痛的发生率差异无统计学意义($P>0.05$),见表2。

3 讨论

虽然同步放化疗可以延长宫颈癌患者的生命周期和改善症状,但其治疗周期比较长,毒副作用比较显著,极容易出现不良反应^[12-14]。放化疗产生的毒副反应常见的有胃肠道不适,恶心呕吐等,甚至顽固性呃逆呕吐,部分患者因这些毒副反应而中断治疗,严重降低了其生存质量^[15,16]。急性呕吐常常发生于给药后的1~2 h,通常能持续大约1个星期。放化疗一方面会降低肿瘤患者的食欲,另一方面,降低机体抵抗力,内环境的紊乱,甚至引起消化道出血^[17,18]。因而,有效控制化疗造成的胃肠道不良反应有助于放化疗的顺利进行。

泮托拉唑具有良好的靶位专一性以及对酸的稳定性,可以特异性地抑制机体胃黏膜细胞的H⁺/K⁺-ATP酶,使壁细胞中的H⁺无法转运入到胃腔内,进而显著降低胃液中的胃酸量,快速提高胃内的pH值,减轻含铂方案化疗物对肿瘤患者胃肠道黏膜造成的直接损伤,有效减轻消化道反应^[19-23]。在强酸的情况下,泮托拉唑能迅速地发生活化,以增强药物的治疗效果。而且泮托拉唑具有抑酸和止血的作用,其半衰期比较长^[24-26]。昂丹司琼能抑制由肠嗜铬细胞释放的5-羟色胺对迷走神经的刺激,有效控制化疗后恶心和呕吐的发生^[27-29]。本研究中,观察组化疗第3、4、5、6 d恶心呕吐的完全缓解率明显高于对照组;与王莹^[30]

等学者的研究类似。该学者发现昂丹司琼联合耳穴压豆治疗宫颈癌术后化疗患者恶心、呕吐反应,结果显示治疗后第2、3、4 d,观察组的呕吐次数、恶心等级均优于对照组,第2、3、4 d,观

察组的呕吐次数、恶心等级均优于第1 d,观察组的恶心、呕吐反应缓解时间均显著短于对照组。

表1 两组恶心呕吐的疗效对比

Table 1 Comparison of the efficacy in the prevention and treatment of nausea and vomiting between two groups

Chemotherapy time	Group	Response level (n)					Complete remission rate (%)
		0 degrees	I degrees	II degrees	III degrees	IV degrees	
Day 1	Control group	32	7	1	0	0	80.00
	Observation group	33	6	0	0	0	84.61
Day 2	Control group	29	9	2	0	0	72.50
	Observation group	31	8	0	0	0	79.49
Day 3	Control group	20	14	5	1	0	50.00
	Observation group	30	8	1	0	0	76.92*
Day 4	Control group	23	10	5	2	0	57.50
	Observation group	31	5	2	1	0	79.49*
Day 5	Control group	26	9	3	2	0	65.00
	Observation group	34	3	1	1	0	87.18*
Day 6	Control group	25	10	3	1	1	62.50
	Observation group	34	2	2	1	0	87.18*

Note: Compared with the control group, *P<0.05.

表2 两组不良反应发生情况的比较[例(%)]

Table 2 Comparison of the incidence of adverse reactions between the two groups[n(%)]

Groups	n	Fatigue	Constipation	Extravertebral Extracorporeal Reaction	Insomnia/Rest- lessness	Diarrhea	Mild Headache
Control group	40	1 (2.50)	3 (7.50)	0 (0.00)	1 (2.50)	1 (2.50)	0 (0.00)
Observation group	39	2 (5.13)	3 (7.69)	0 (0.00)	0 (0.00)	0 (0.00)	0 (0.00)

研究表明 80%~90% 接受放化疗的癌症患者均会出现疲乏症状,放化疗可以使疲乏症状的严重程度加重^[32]。宫颈癌患者经过长时间的放化疗而导致的痛苦及紧张后,容易出现持续的、痛苦的、主观的疲惫感或乏力感等癌因性疲乏感觉,主要包括注意力不集中、身体虚弱、兴趣减少以及活动无耐力等,常伴有功能障碍,严重影响了患者家庭、身体、社会和心理功能。本研究中,观察组的癌因性疲乏评分明显低于对照组。其原因可能为昂丹司琼联合泮托拉唑对同步化疗所致恶心呕吐具有更加显著的效果,患者由于胃肠道不良反应减轻,疲乏症状也随之减轻。目前,临床还没有制定应用昂丹司琼和泮托拉唑治疗宫颈癌放化疗后的癌因性疲乏的规范治疗方案,但是中医治疗方法在治疗宫颈癌放化疗后的癌因性疲乏有很多研究。如张莹莹^[33]等学者发现六君子汤治疗宫颈癌辅助放化疗患者,可使患者的癌因性疲乏得到显著减轻;曹莹^[34]采用穴位艾灸治疗宫颈癌同步放化疗患者癌因性疲乏,结果也显示穴位艾灸可以有效降低宫颈癌同步放化疗患者癌因性疲乏的症状并提高宫颈癌同步放化疗患者睡眠质量、缓解其焦虑情绪与疲乏症状。本研究结果显示两组的乏力嗜睡、便秘、椎体外系反应、失眠/不安、腹泻、轻度头痛的发生率无明显差异。陈莉^[31]等学者的研究显示盐酸昂丹司琼联合泮托拉唑可预防化疗引起的恶心呕吐,毒副反应轻。其原因可能为泮托拉唑不会对诱导肝细胞的活性

产生抑制,因此不会对其他药物的代谢造成影响,明显降低药物之间的相互作用,安全性较高。

综上所述,昂丹司琼联合泮托拉唑不但对宫颈癌同步化疗所致恶心呕吐有显著的疗效,还能明显减轻癌因性疲乏,且安全性高。本研究为临床治疗宫颈癌同步化疗所致恶心呕吐提供了参考,但是也存在一定的不足,如纳入的样本少,并且没有设立昂丹司琼单独治疗组,因此在后续研究中,需要扩大样本量,设立更详细的组别,深入探究昂丹司琼联合泮托拉唑治疗宫颈癌同步化疗所致恶心呕吐的机制,为药物的临床应用提供思路。

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