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三维适形放疗联合替吉奥胶囊口服化疗治疗局部晚期胃癌疗效观察

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摘要 目的:探讨三维适形放疗联合替吉奥胶囊口服化疗治疗局部晚期胃癌的疗效及安全性。**方法:**收取2010年1月至2015年1月于我院治疗的局部晚期胃癌患者126例作为研究对象进行回顾性分析,根据治疗方法的不同将其分为观察组65例及对照组61例。对照组患者仅进行三维适形放疗,观察组在此基础上加用替吉奥胶囊口服。对两组患者近期疗效、不良反应发生情况、生活质量以及远期疗效进行观察与比较。**结果:**观察组患者RR及DCR分别为67.69%及87.69%,对照组RR及DCR分别为34.43%及67.21%,观察组近期疗效明显优于对照组($P<0.05$)。观察组患者各系统不良反应发生率高于对照组,但差异不显著($P>0.05$)。观察组患者生活质量改善总有效率为86.15%,明显高于对照组70.49%。观察组患者1年生存率明显高于对照组($P<0.05$),但3年生存率及5年生存率两组相差并不显著($P>0.05$)。**结论:**三维适形放疗联合替吉奥胶囊口服具有良好的临床疗效,有助于提高患者生存率及生存质量,但可能会提高不良反应发生风险,需根据患者具体情况设计治疗方案。

关键词: 局部晚期胃癌;三维适形放疗;替吉奥;疗效

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Clinical Effect of 3D-CRT Combined with Tegafur Gimeracil Oteracil Capsule in Treatment of Locally Advanced Gastric Cancer

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ABSTRACT Objective: To explore the clinical effect and safety of 3-dimensional conformal radiation therapy (3D-CRT) combined with tegafur gimeracil oteracil capsule (S-1) in treatment of locally advanced gastric cancer. **Methods:** 126 patients accepted in our hospital from January 2010 to January 2015 were retrospectively analyzed and divided into observation group with 65 cases and control group with 61 cases according to different treatment methods. The patients in control group were given 3D-CRT only, but the patients in observation group were given S-1 additionally. Then the short-term effect, adverse reactions, life quality and long-term effect of two groups were observed and compared. **Results:** The RR and DCR of observation group was 67.69 % and 87.69 % respectively, and the RR and DCR of control group was 34.43 % and 67.21 % respectively. The short-term effect of observation group was obviously better than that of control group with statistically significance ($P<0.05$). The adverse reactions of each systems of observation group were higher than those of control group but without statistically difference ($P>0.05$). The improvement rate of life quality in observation group was 86.15 %, which was obviously higher than 70.49 % of control group with statistically significance ($P<0.05$). 1-year survival rate of observation group was remarkably higher than that of control group but there was no statistically difference in 3-year and 5-year survival rate between two groups ($P>0.05$). **Conclusions:** Using 3D-CRT combined with S-1 has good effect and is helpful improving survival rate and life quality, but it will also improve the risk of adverse reactions. The treatment methods must be designed according to patients' specific conditions.

Key words: Locally advanced gastric cancer; 3D-CRT; Tegafur gimeracil oteracil capsule; Effect

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前言

胃癌是最为常见的恶性肿瘤之一,占我国消化道恶性肿瘤的首位,其发病率及死亡率均较高,引起了临床工作者的广泛关注^[1]。随着科学技术的进展,胃癌治疗效果及患者预后得到了一定的改善,然而仍有许多患者因缺乏典型症状或体征而无法进行早期诊断,发现时已到晚期,此类患者往往具有较差的预

后情况及生存率^[2]。针对胃癌的治疗以手术治疗为主,但晚期胃癌患者多已失去手术指征^[3]。近年来,国内外有研究采用三维适形放疗联合化疗的手段治疗局部晚期胃癌,取得了良好的临床疗效,但此类研究常以铂类药物为主,具有较为严重的毒副反应。此外,其研究多是对疗效及安全性进行考察,缺乏对患者生活质量改善情况的比较^[4]。故本研究对我院近年来收治的局部晚期胃癌患者以不同方法进行治疗,并对其疗效、安全性以及生活质量进行比较,以期合理治疗方案的制定提供理论依据。现报道如下。

1 资料与方法

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1.1 一般资料

研究对象:2010 年 1 月~2015 年 1 月 126 例局部晚期胃癌患者。纳入标准:① 所有患者均经明确的病理学及影像学诊断确诊为局部晚期胃癌;② 患者年龄在 18~75 岁之间;③ 患者均不具有手术治疗指征;④ 预计生存期 >3 个月。排除标准:①

合并其他系统严重疾病;② 合并精神类疾病,无法配合治疗;③ 具有相关药物使用禁忌症。按照治疗方法的不同,将 126 例患者分为观察组 65 例及对照组 61 例,其中观察组包含男性 36 例,女性 29 例;对照组包含男性 32 例,女性 29 例。两组患者基线资料无显著差异($P>0.05$),有可比性。见表 1。

表 1 两组患者基线资料比较
Table 1 Comparison of the basic data of two groups

Items	Observation group(n=65)	Control group(n=61)	P
Gender [n(%)]			>0.05
Male	36(55.38)	32(52.46)	
Female	29(44.62)	29(47.54)	
Age(years, $\bar{x} \pm s$)	49.3 $\pm$ 8.6	48.5 $\pm$ 9.1	>0.05
TNM Stage [n(%)]			>0.05
Stage III	39(60.00)	34(55.74)	
Stage IV	26(40.00)	27(44.26)	
Pathological Types [n(%)]			>0.05
High differentiation adenocarcinoma	12(18.46)	12(19.67)	
Medium differentiation adenocarcinoma	37(56.92)	32(52.46)	
Low differentiation adenocarcinoma	16(24.62)	17(27.87)	
EOCG scores [n(%)]			>0.05
1	32(49.23)	31(50.82)	
2	33(50.77)	30(49.18)	

1.2 治疗方法

采用瑞典医科达直线加速器进行三维适形放疗,放疗前首先使用 CT 进行模拟定位。模拟定位前及每次治疗之前所有患者均需禁食 3 h,口服 20%泛影葡胺 +200 mL 温水以使胃部显影。嘱患者取平卧位,使用热塑膜进行体位固定,在平静呼吸状态下进行 CT 增强扫描,扫描范围为膈上 5 cm 左右至脐水平,层厚 5 mm,将扫描数据上传至三维治疗计划系统。勾画肿瘤靶区(GTV,即 CT 增强扫描所显示的肿区,包括原发病灶及肿大淋巴结)、临床靶区(CTV,即 CT 增强扫描所示的原发肿瘤及对应的淋巴结引流区,为 GTV 外放 5 mm)、计划靶区(PTV,为 CTV 基础上上下腹背扩大 1.0~2.0 cm,左右扩大 0.5~1.5 cm)以及正常组织器官如双肾、肝脏、脊髓等。放射剂量:45~60 Gy/(30f·qd),于每周一至周五进行放疗,依据患者情况照射 4~8 周。观察组在此基础上加用替吉奥胶囊口服,具体用法为替吉奥胶囊(生产厂家:齐鲁制药有限公司;批准文号:国药准字 H20100151)口服化疗,按照患者体表面积调整剂量,体表面积 <1.25 m² 的患者给予 40 mg/次,体表面积 1.25~1.5 m² 的患者给予 50 mg/次,体表面积 $\geq$ 1.5 m² 的患者给予 60 mg/次。2 次/d,治疗两周后休息一周,以此为一个疗程,共进行 2 个疗程治疗。

1.3 观察指标

对两组患者近期疗效、不良反应发生情况、生活质量以及远期疗效进行观察与比较,具体内容如下:① 近期疗效^[9]:使用 RECIST 疗效评价标准,将患者近期疗效分为完全缓解(CR)、部分缓解(PR)、疾病稳定(SD)以及疾病进展(PD)。完全缓解 + 部分缓解 = 总有效率(RR),完全缓解 + 部分缓解 + 疾病稳定 = 疾病控制率(DCR);② 不良反应发生情况:主要包括血液系统毒性、消化系统毒性以及其他;③ 生活质量^[9]:对治疗结束后两组患者生活质量改善情况进行比较,使用 KPS 评分进行评价,分为改善(评分增加 $\geq$ 10 分),稳定(评分变化不超过 10 分),无效(评分减少 $\geq$ 10 分),改善 + 稳定 = 总有效;④ 远期疗效:对两组患者进行为期五年的随访以考察其生存率。

1.4 统计学方法

使用 SPSS 18.0 软件,本研究计数数据以百分比形式表示,组间行卡方检验。以 $P<0.05$ 为差异显著,有统计学意义。

2 结果

2.1 两组近期疗效比较

观察组 RR 及 DCR 分别为 67.69% 及 87.69%,对照组 RR 及 DCR 分别为 34.43% 及 67.21%,观察组近期疗效明显优于对照组($P<0.05$)。见表 2。

表 2 两组近期疗效比较[n(%)]

Table 2 Comparison of short-term effect of two groups [n(%)]

Groups	n	CR	PR	SD	PD	RR	DCR
Observation group	65	12(18.46)	32(49.23)	13(20.00)	8(12.31)	44(67.69)	57(87.69)
Control group	61	4(6.56)	17(27.87)	20(32.79)	20(32.79)	21(34.43)	41(67.21)
P						<0.05	<0.05

2.2 两组不良反应发生情况比较

对两组患者不良反应进行观察,主要包括血液系统不良反应(白细胞减少、红细胞减少、血小板减少)、消化系统不良反应(恶心呕吐、腹泻)以及其他不良反应(口腔粘膜炎、疲乏、周围

神经毒性)。两组出现的不良反应均以轻度(I~II度)为主,经对症治疗有所缓解。观察组各系统不良反应发生率均高于对照组,但无统计学差异($P>0.05$)。见表3。

表 3 两组不良反应发生情况比较[n(%)]

Table 3 Comparison of incidence of adverse reactions of two groups [n(%)]

Groups	n	Grade	Hematologic System			Digestive system		Others		
			Leukopenia	Erythrope- nia	Thrombo- cytopenia	Nausea and vomiting	Diarrhea	Oral mucositis	Tired	Periphery neurotoxicity
Observation group	65	I~II	14(21.54)	8(12.31)	6(9.23)	6(9.23)	5(7.69)	3(4.62)	4(6.15)	5(7.69)
		III~IV	3(4.62)	2(3.08)	0(0.00)	5(7.69)	4(6.15)	1(1.54)	0(0.00)	0(0.00)
		Total	17(26.15)	10(15.38)	6(9.23)	11(16.92)	9(13.85)	4(6.15)	4(6.15)	5(7.69)
Control group	61	I~II	8(13.11)	6(9.84)	3(4.92)	4(6.56)	3(4.92)	2(3.28)	3(4.92)	2(3.28)
		III~IV	2(3.28)	1(1.64)	0(0.00)	2(3.28)	1(1.64)	0(0.00)	0(0.00)	0(0.00)
		Total	10(16.39)	7(11.48)	3(4.92)	6(9.84)	4(6.56)	2(3.28)	3(4.92)	2(3.28)

2.3 两组生活质量改善情况比较

%,观察组生活质量改善情况明显优于对照组($P<0.05$)。见表4。

观察组生活质量改善总有效率为 86.15 %,对照组为 70.49

表 4 两组生活质量改善情况比较[n(%)]

Table 4 Comparison of life quality improvement of two groups [n(%)]

Groups	n	Improvement	Stable	Inefficient	Total effective rate
Observation group	65	22(33.85)	28(43.08)	9(13.85)	56(86.15)
Control group	61	14(22.95)	29(47.54)	18(29.51)	43(70.49)
P					<0.05

2.4 两组远期疗效比较

观察组完成随访 1 年、3 年及 5 年的患者例数分别为 65 例、26 例以及 6 例;对照组完成随访 1 年、3 年及 5 年的患者例数分别为 61 例、15 例以及 1 例。观察组 1 年生存率为 52.31 % (34/65), 3 年生存率为 35.80 % (9/26), 5 年生存率为 33.33 % (2/6); 对照组 1 年生存率为 32.79 % (20/61), 3 年生存率为

20.00 % (3/15), 5 年生存率为 0(0/1)。观察组患者 1 年生存率明显高于对照组($P<0.05$),但 3 年生存率及 5 年生存率两组相差不显著($P>0.05$)。见表 5。

3 讨论

作为消化系统最为常见的恶性肿瘤之一,针对胃癌的治疗

表 5 两组远期疗效比较

Table 5 Comparison of long-term effect of two groups

Groups	1-year survival rate	3-year survival rate	5-year survival rate
Observation group	52.31%(34/65)	35.80%(9/26)	33.33%(2/6)
Control group	32.79%(20/61)	20.00%(3/15)	0.00%(0/1)
P	<0.05	>0.05	>0.05

方案多以手术为主,化疗为辅。在以往的治疗当中较少采用放疗进行治疗,这是因为胃癌多为腺癌,对放射治疗敏感性较差,在达到杀灭肿瘤细胞剂量时往往可同时对正常胃黏膜造成损伤^[7]。此外,从解剖学进行分析,胃癌的生理位置关键,其放疗视野内覆盖着肝脏、小肠、肾脏等诸多重要脏器,这些脏器对放射治疗的耐受剂量都很低,较易引起放射性损伤^[8]。随着技术的不断进步,三维适形放疗逐渐开始应用到人类肿瘤的治疗当中,其最早的应用方向为头颈部肿瘤,之后被越来越多的应用到其他多种肿瘤的治疗当中^[9-11]。三维适形放疗是一种具有高精度的放射治疗方法,其工作原理是利用CT增强扫描图像模拟并重建肿瘤的三维立体结构,在不同方向设置不同照射野,并使用与肿瘤病灶形状一致的适形挡铅,可以使高剂量曲线在三维方向与靶区形状吻合,以此提高对肿瘤靶区的照射剂量,减少对其他正常组织的照射剂量^[12,13]。研究报道显示,三维适形放疗较传统放射治疗而言具有明显优势,因此已成为肿瘤放疗领域的主要技术^[14]。

然而有研究报道显示,单纯放疗仍然无法获得令人满意的治疗效果,其原因可能是放射剂量不足或肿瘤发生远处转移所致^[15]。因此,采用放疗同步化疗的治疗方案可对单纯放疗起有效弥补及增敏作用,近年来已在临床研究中得到了较多报道^[16,17]。替吉奥胶囊作为新一代的氟尿嘧啶类药物,具有良好的生物利用度,已成为胃癌的一线治疗药物^[18]。对其成分进行研究,替吉奥胶囊由替加氟、吉美嘧啶和奥替拉西钾以1:0.4:1的组成比复合而成。其中替加氟为5-氟尿嘧啶的前体药物,半衰期长达12h,具有良好的抗肿瘤作用;吉美嘧啶对5-氟尿嘧啶分解代谢酶具有选择性拮抗作用,可维持其高浓度持续存在,增强其抗肿瘤作用;奥替拉西钾亦具有抑制5-氟尿嘧啶转化的作用。三种药物联合作用,可稳固其抗肿瘤效果^[19]。

本研究参考他人报道,采用三维适形放疗联合替吉奥胶囊进行治疗,取得了较为显著的临床疗效。余一锋等研究报道显示,采用三维适形放疗同步替吉奥联合奥沙利铂对局部晚期胃癌进行治疗,RR为76.3%,略高于本文联合治疗组的67.69%,且不具有统计学意义^[20]。但该报道仅对联合治疗疗效进行了观察,缺少对单独进行三维适形放疗效果的考察,并且该研究仅纳入38例患者,在患者数量上也远远低于本研究。本研究中,观察组RR及DCR均明显高于对照组,证实了两种方案联合治疗的确由于单独放疗。在不良反应方面,观察组血液学毒性、消化道毒性以及其他毒性均较对照组高,但不具有显著差异。此外,两组不良反应均以轻度为主,经过积极的对症治疗和营养支持均可缓解,不会对患者产生明显影响,具有良好的耐受性。而在远期疗效方面,观察组仅在1年生存率方面高于对照组,而3年及5年生存率两组并无差异。这可能是因为观察例数过少所致,笔者也会在今后的研究当中对此方面内容进行完善。

与其他研究不同的是,本文对两组患者的生存质量进行了考察与比较。结果显示,观察组患者生存质量恢复情况明显优于对照组,提示采用联合治疗方案可使患者生理及心理方面得到一定改善,从而树立生活的信心与克服疾病的勇气,对于改善患者预后、延长生存期等方面均可能具有积极的意义。

综上所述,三维适形放疗联合替吉奥胶囊口服治疗局部晚

期胃癌具有良好的临床疗效,有助于提高患者生存率及生存质量,但可能会提高不良反应发生风险,需根据患者具体情况设计治疗方案。

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